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(54) **PROSTHETIC HEART VALVE HAVING IDENTIFIERS FOR AIDING IN RADIOGRAPHIC POSITIONING**

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CPC ***A61F 2/2418*** (2013.01); ***A61B 34/20*** (2016.02); ***A61F 2/2436*** (2013.01); *A61B 2090/376* (2016.02); *A61F 2220/0016* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2230/005* (2013.01); *A61F 2230/008* (2013.01); *A61F 2230/0054* (2013.01); *A61F 2250/0098* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/2409; A61F 2/2418; A61F 2/2236; A61F 2250/0096–0098
See application file for complete search history.

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(57) **ABSTRACT**

A prosthetic heart valve having identifiers for aiding in radiographic positioning is described.

20 Claims, 8 Drawing Sheets

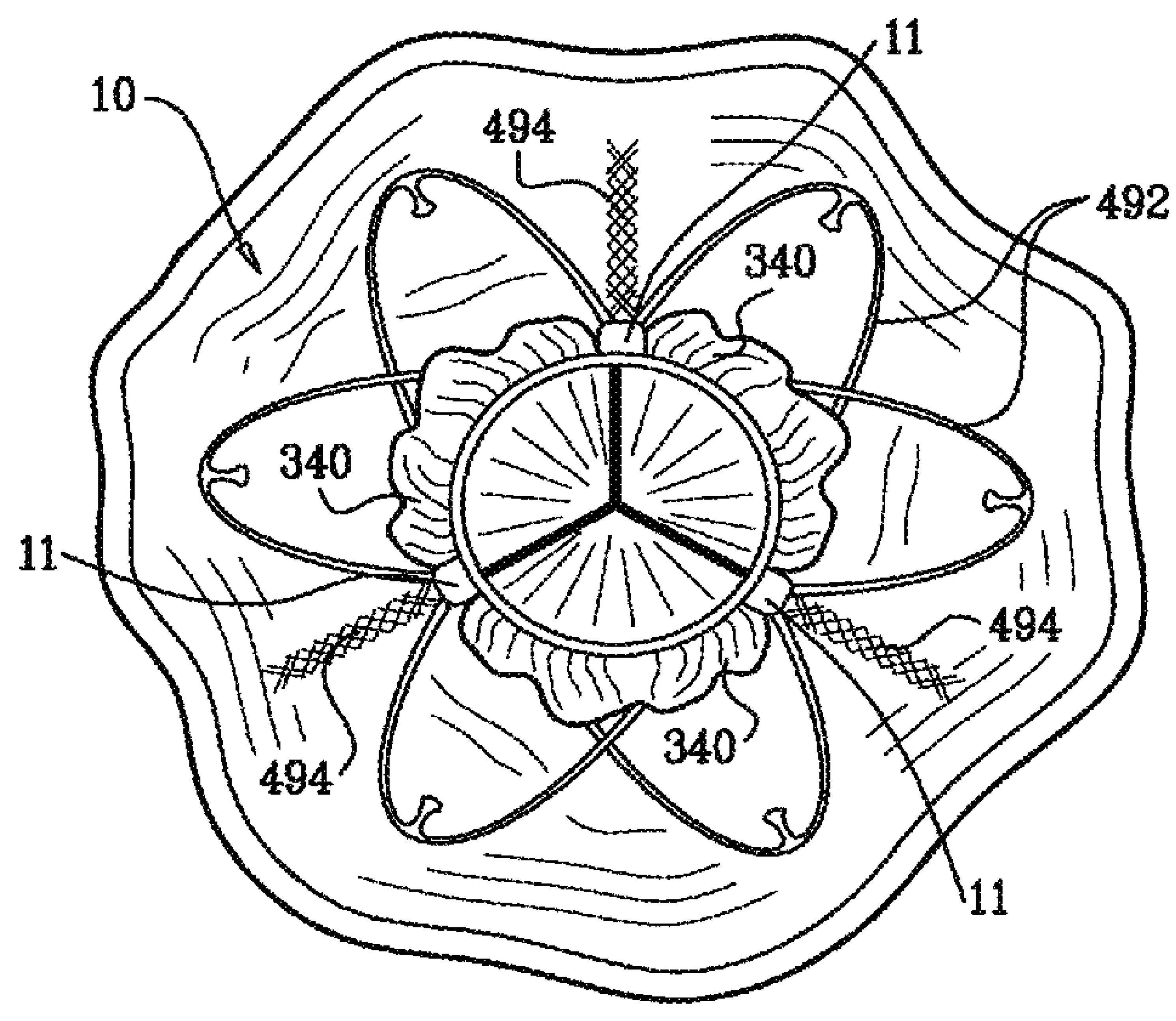

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FIG. 1

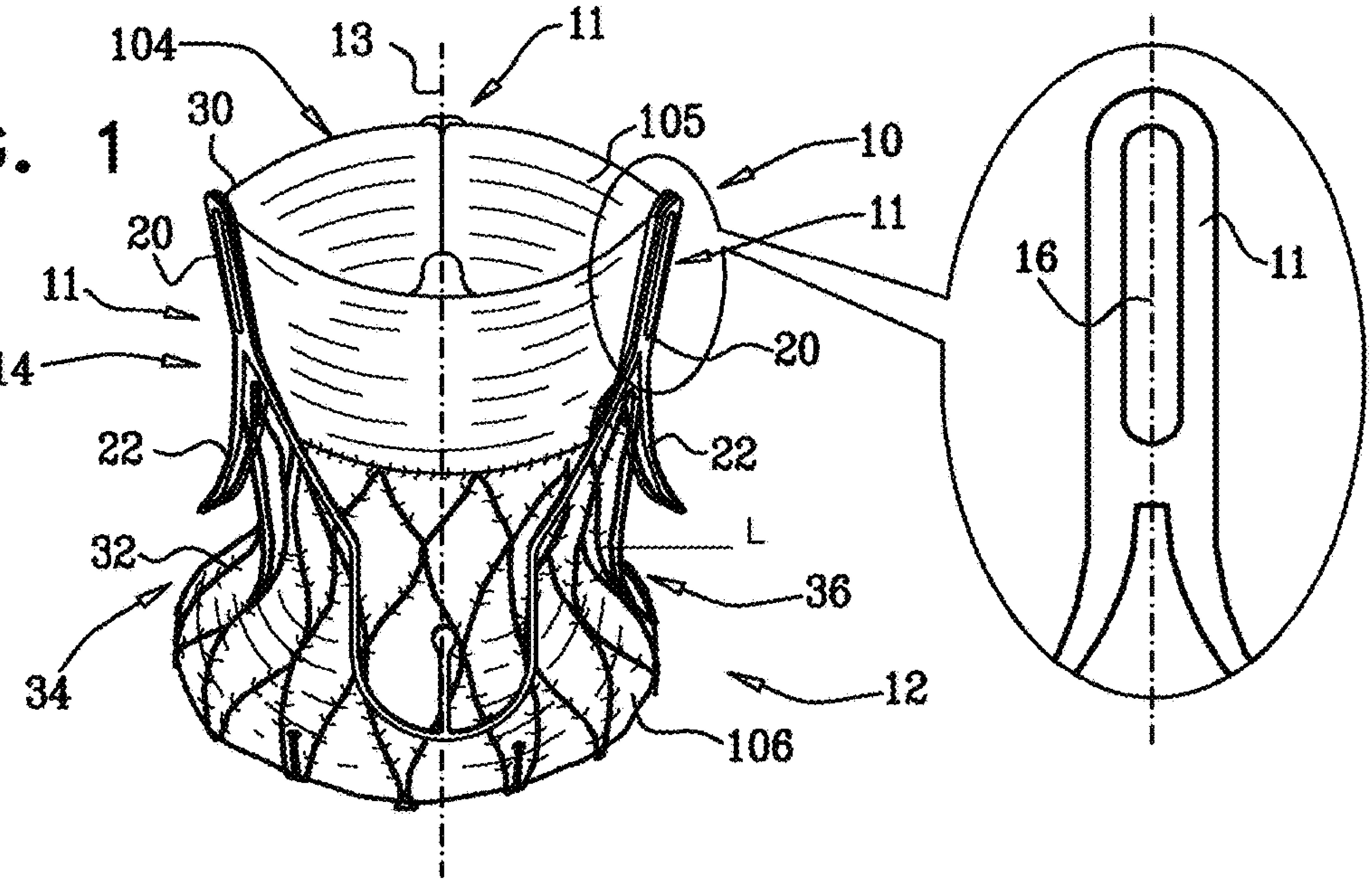


FIG. 2A

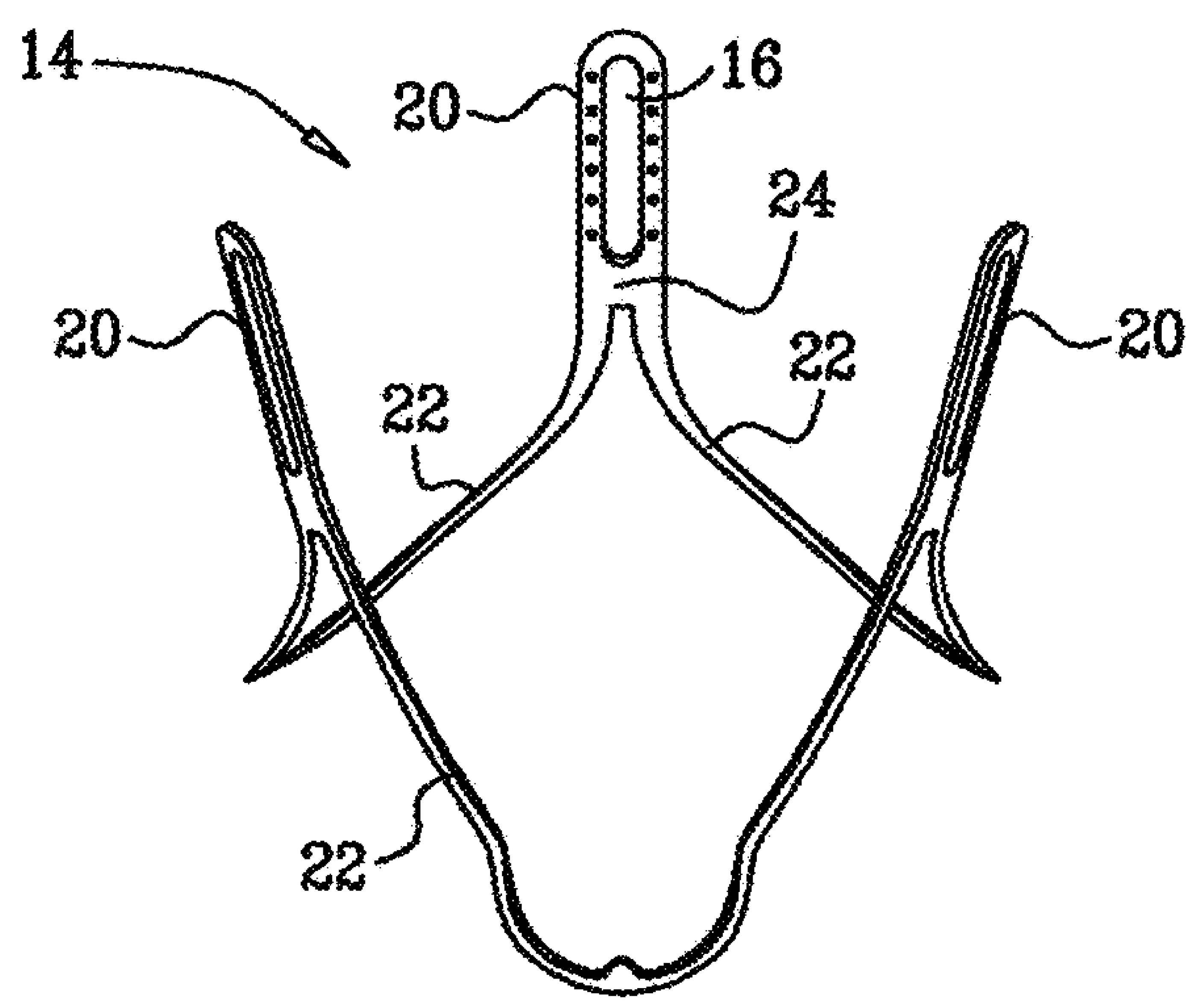
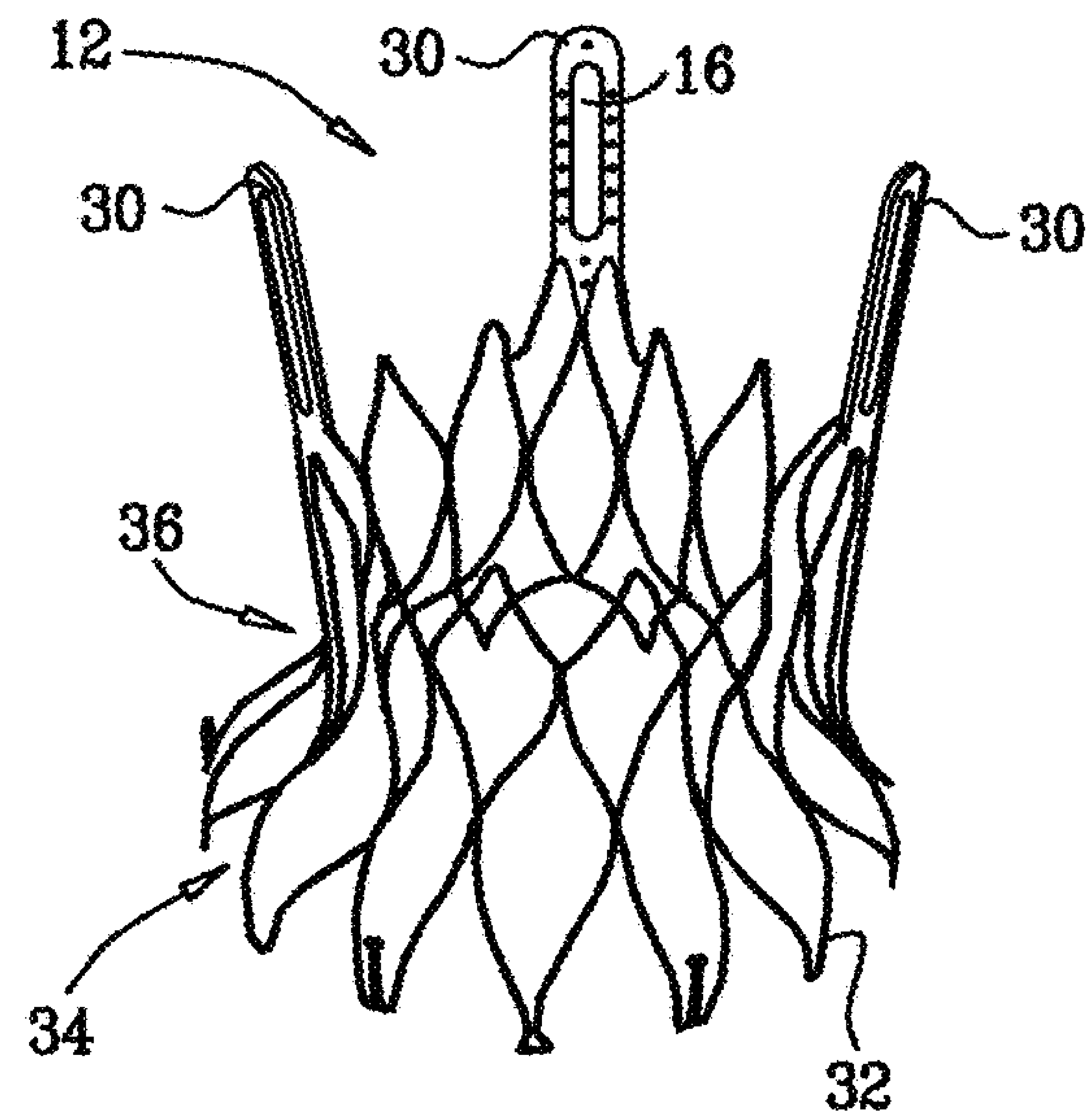


FIG. 2B



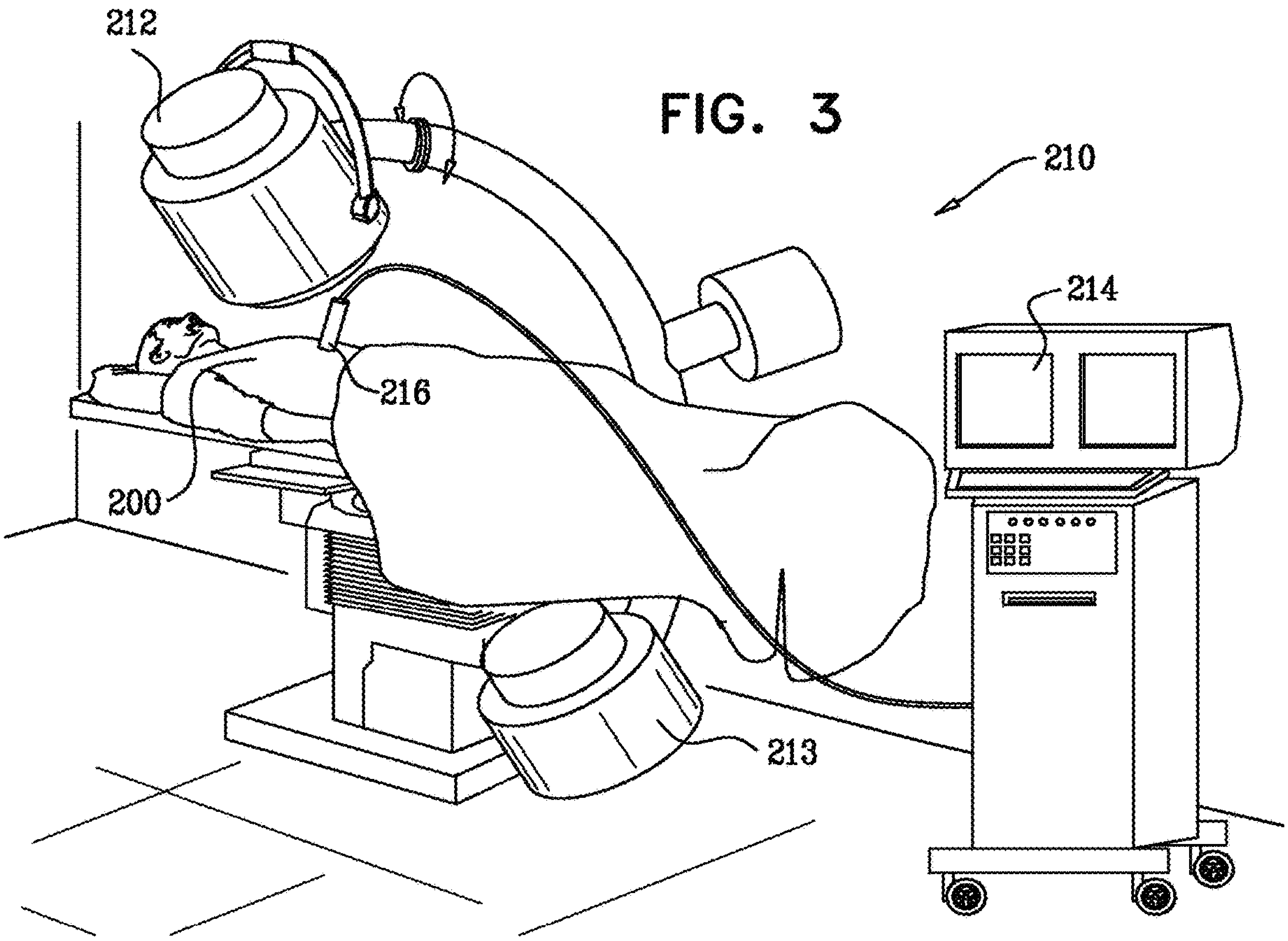
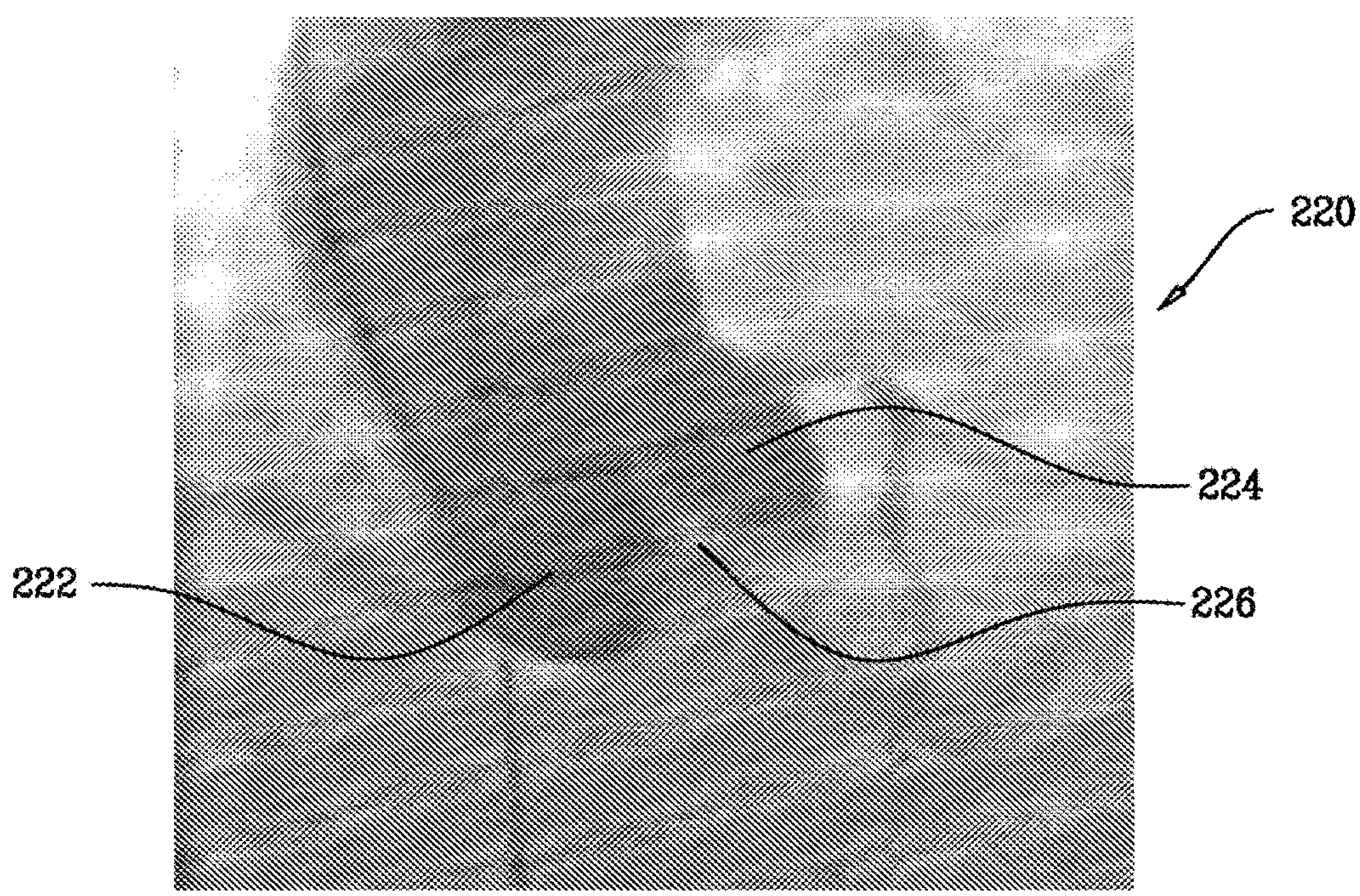


FIG. 3

FIG. 4



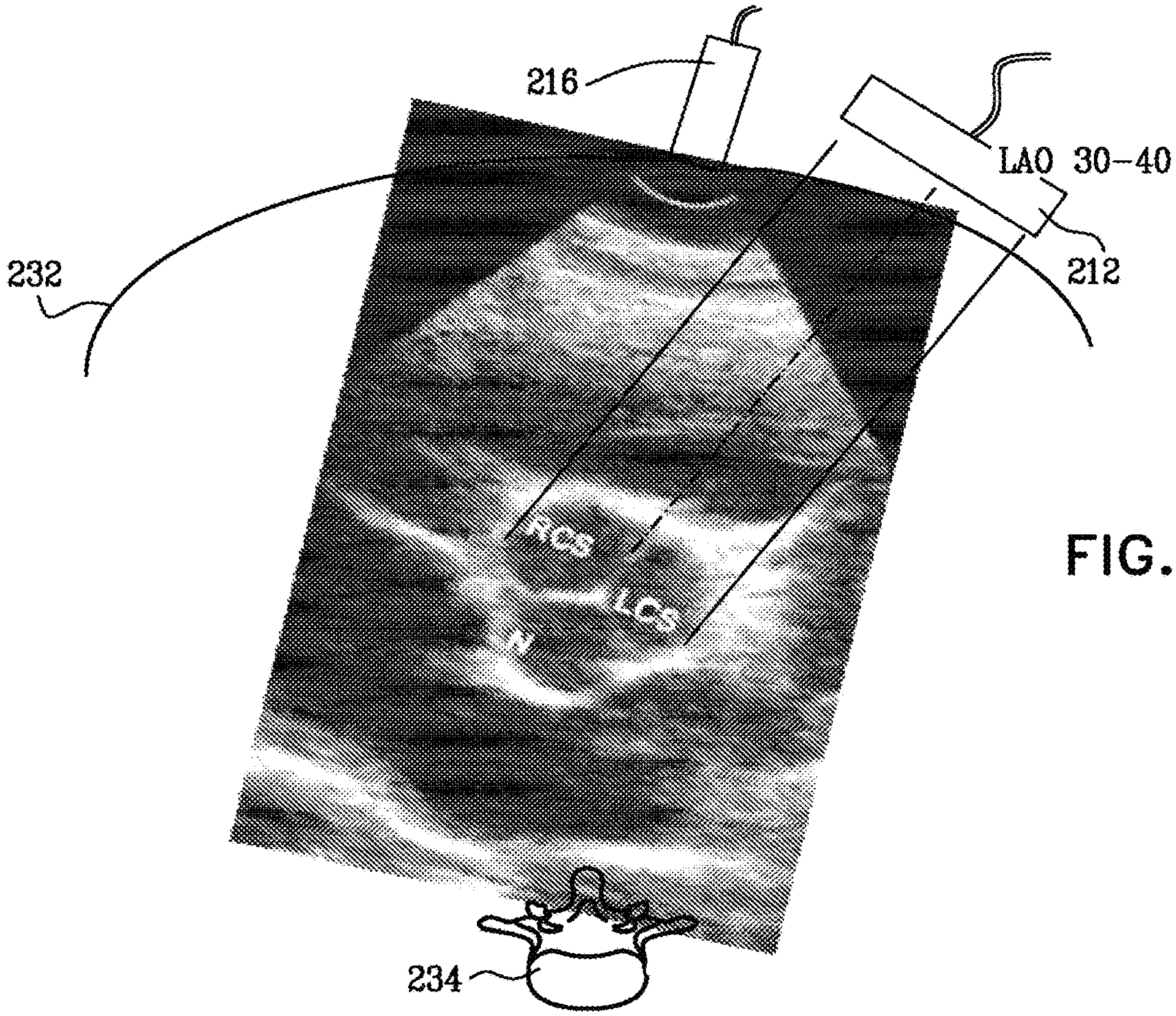


FIG. 5

FIG. 6A

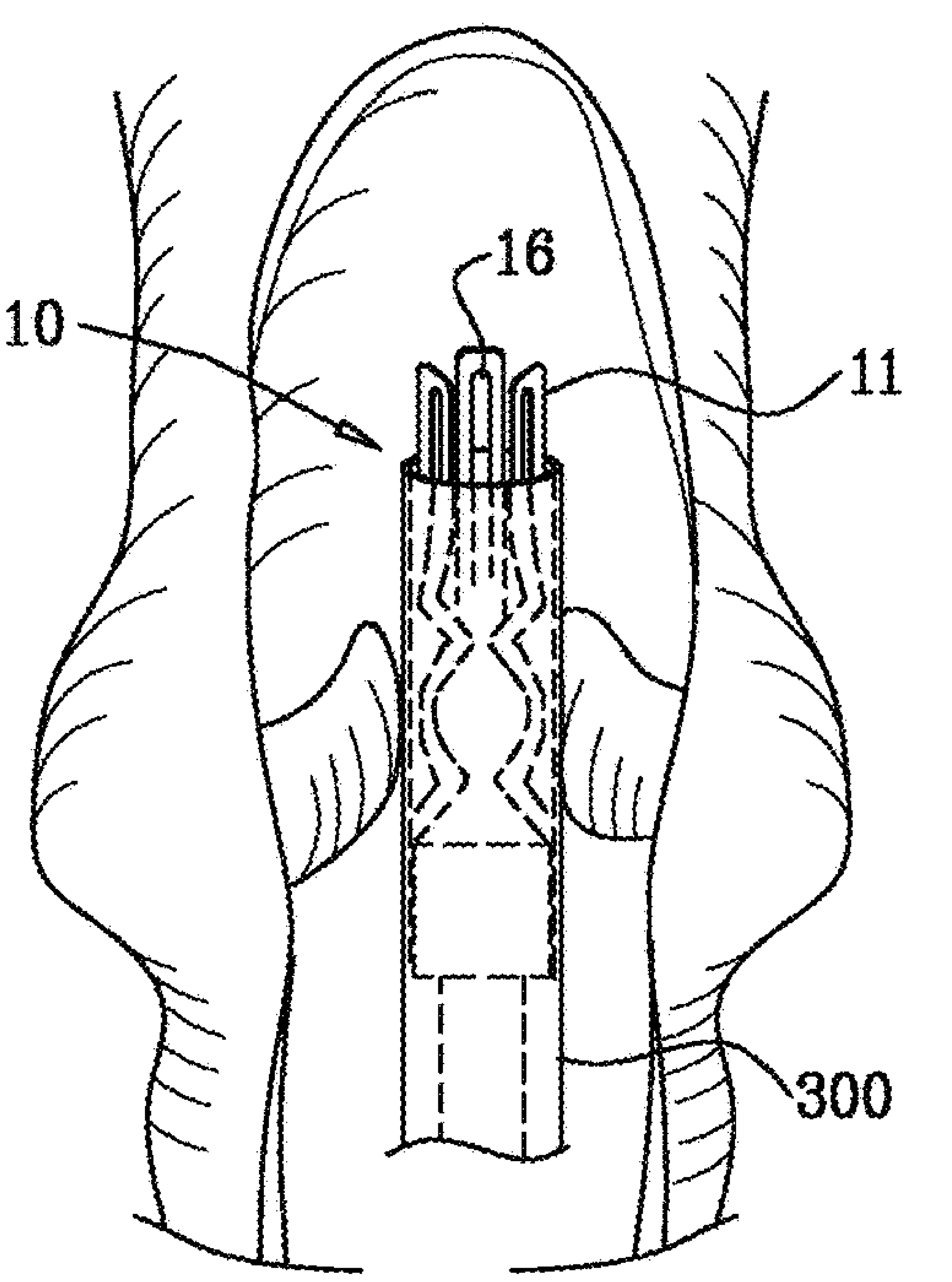
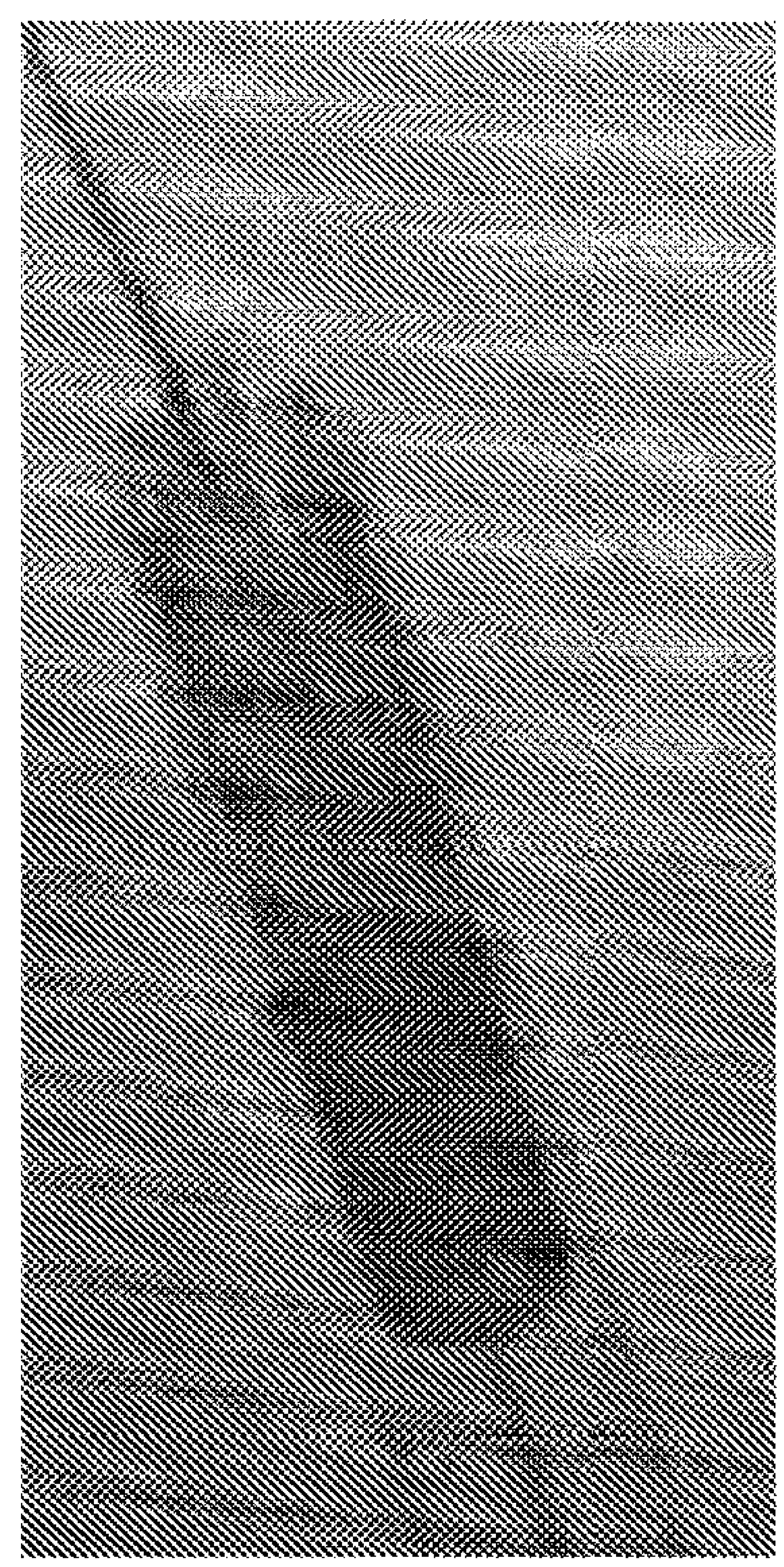


FIG. 6B



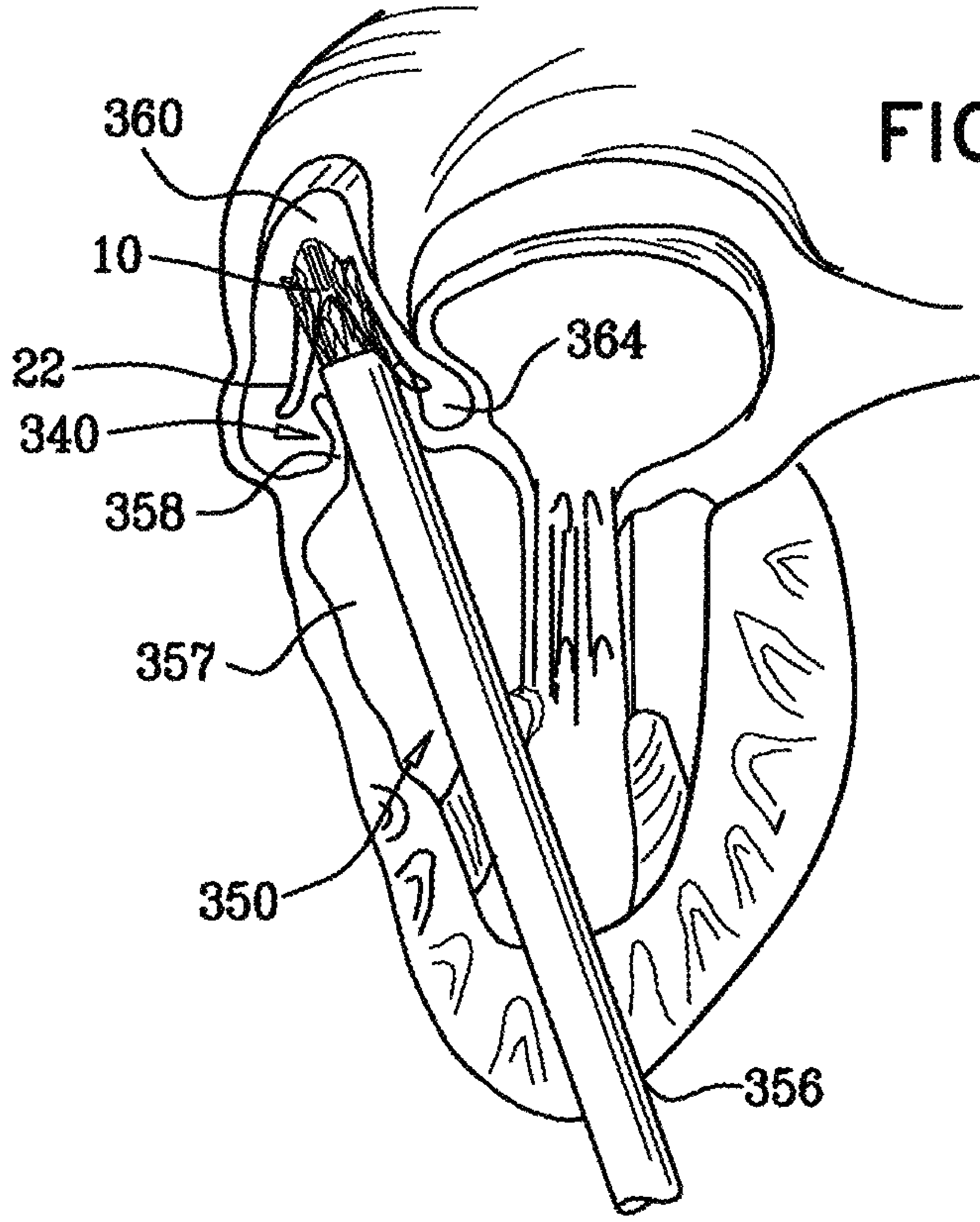

360
10
22
340
358
357
350
364
356

FIG. 7A

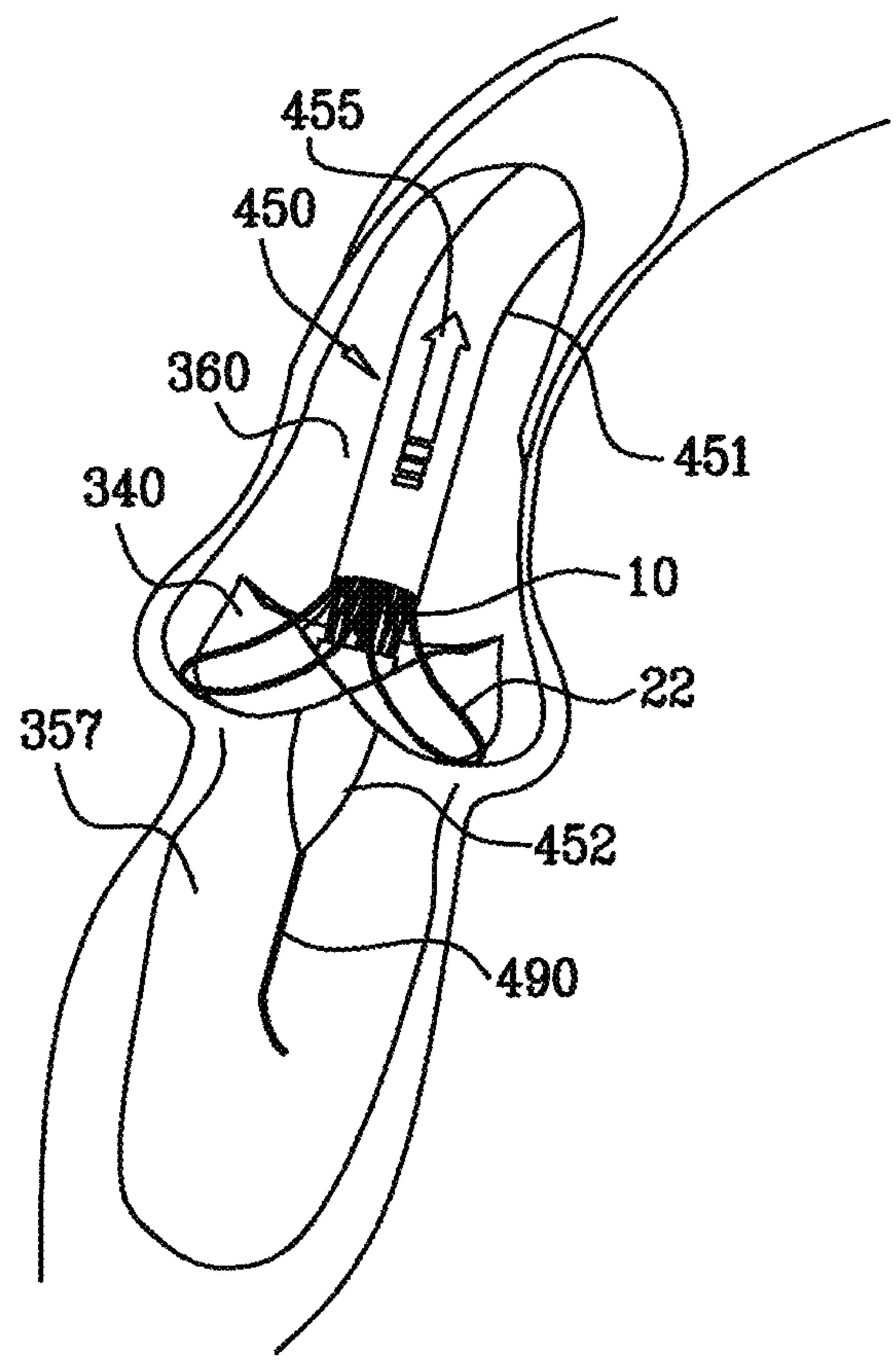

455
450
360
340
357
451
10
22
452
490

FIG. 7B

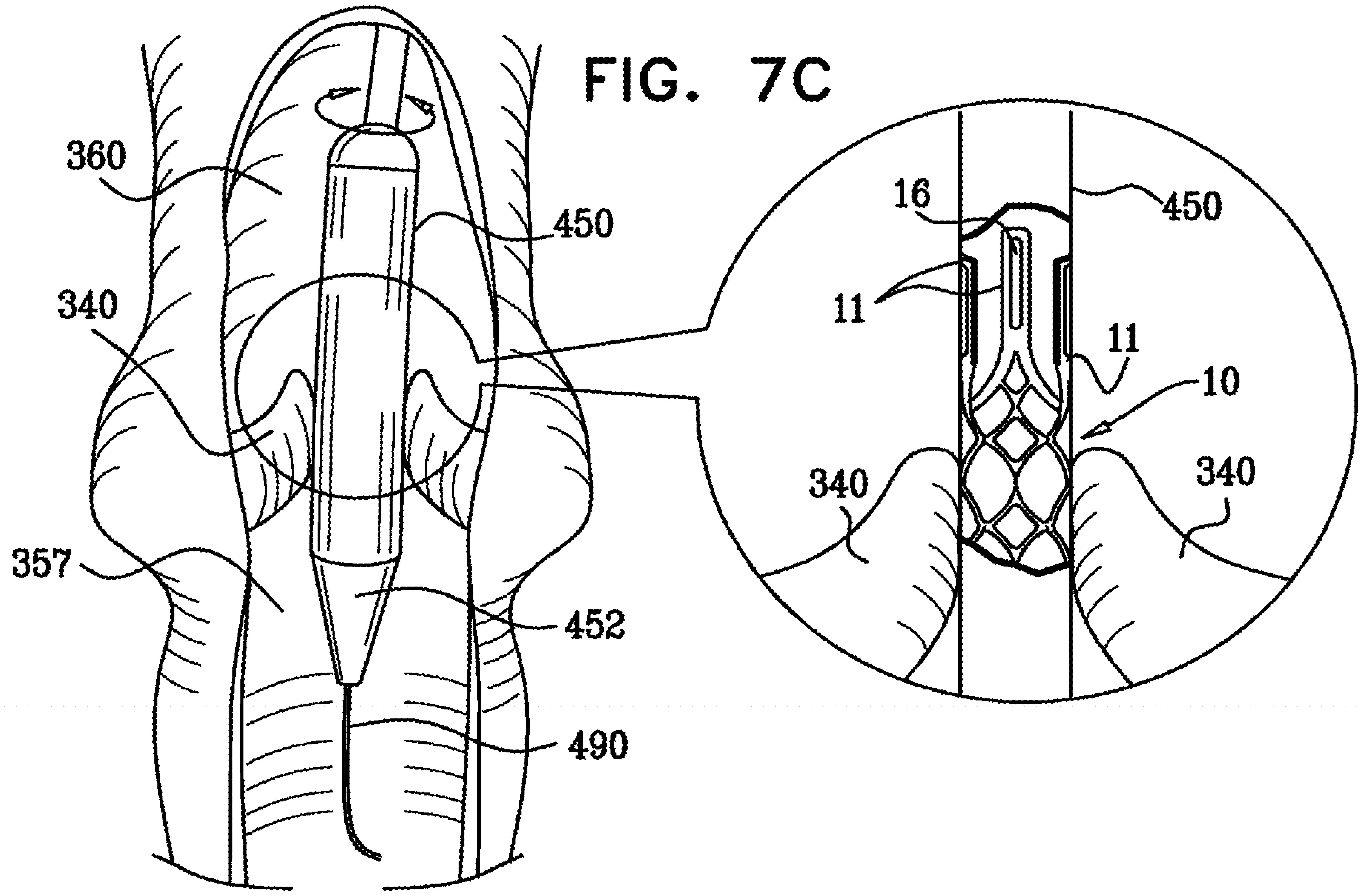

360
450
340
357
452
490
16
450
11
11
10
340
340

FIG. 7C

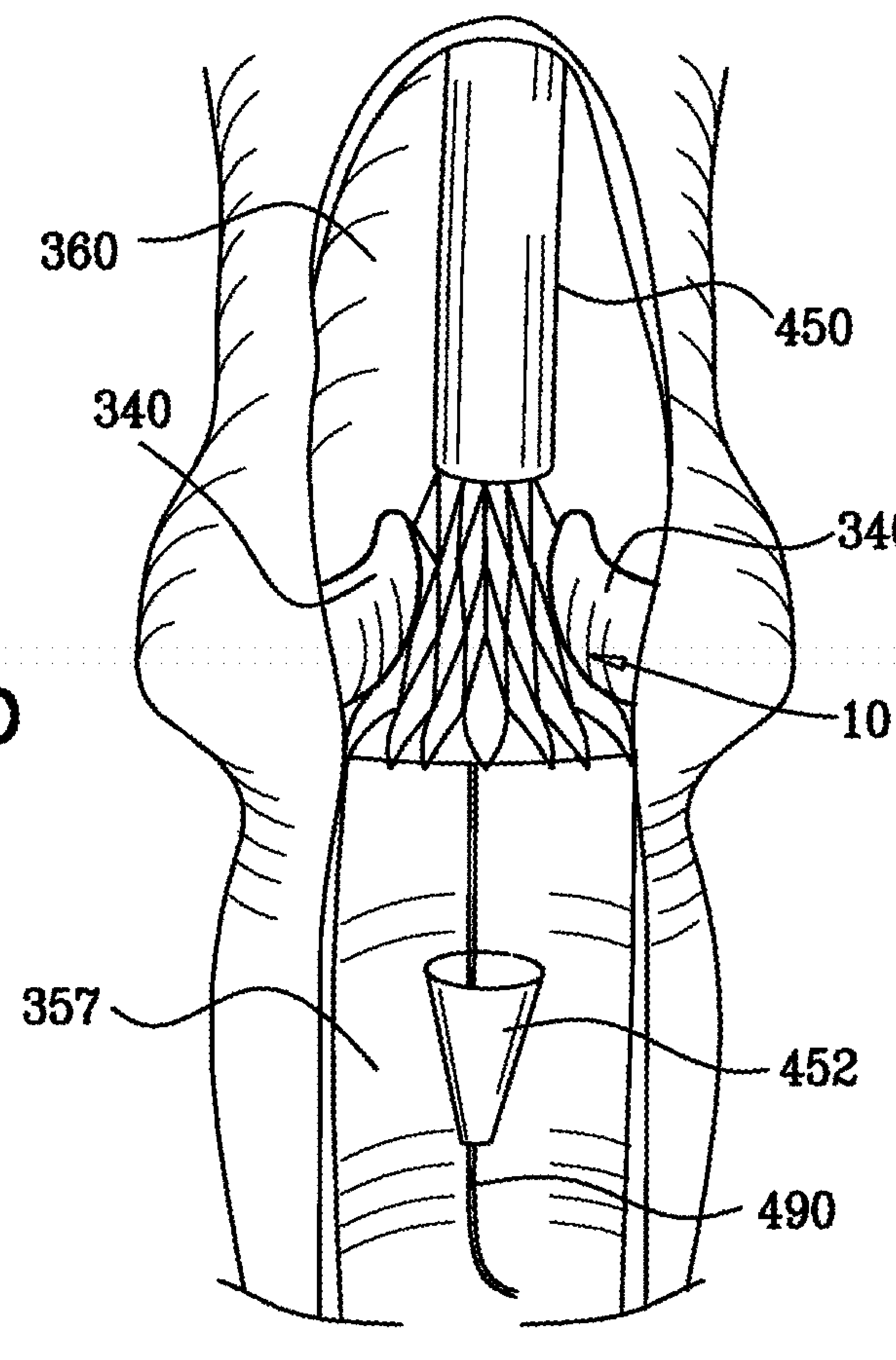
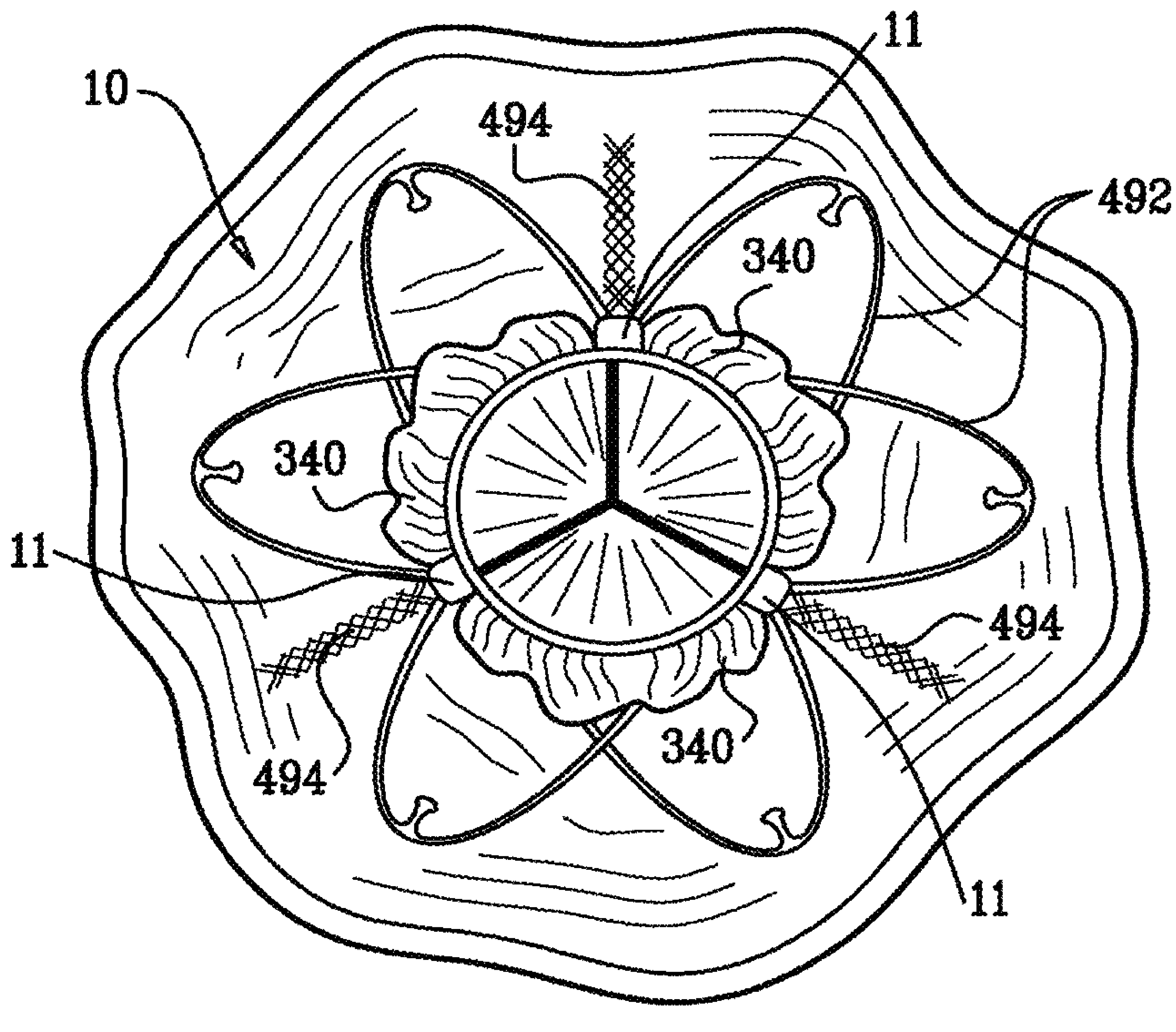

360
450
340
340
10
357
452
490

FIG. 7D

FIG. 7E



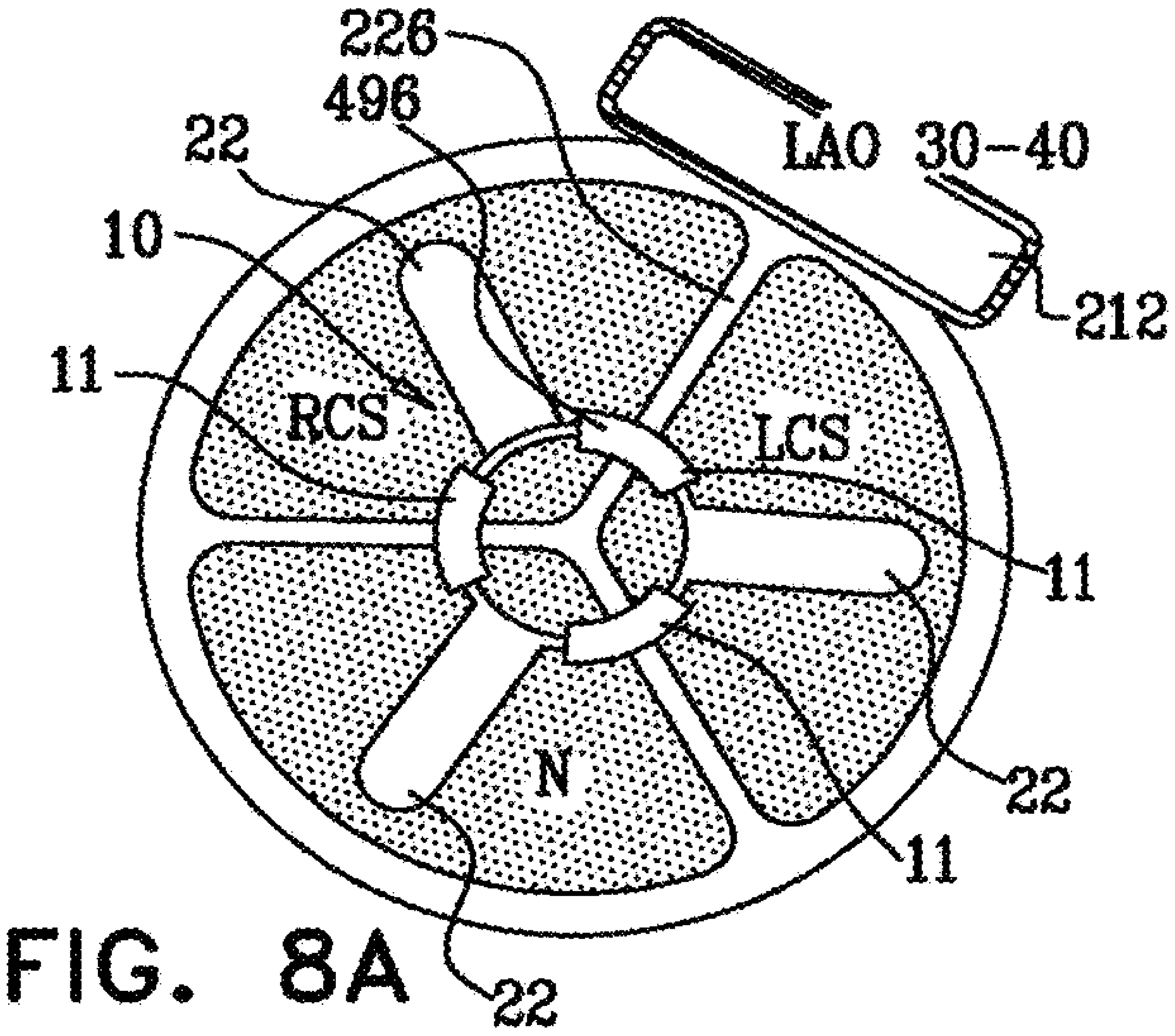


FIG. 8A

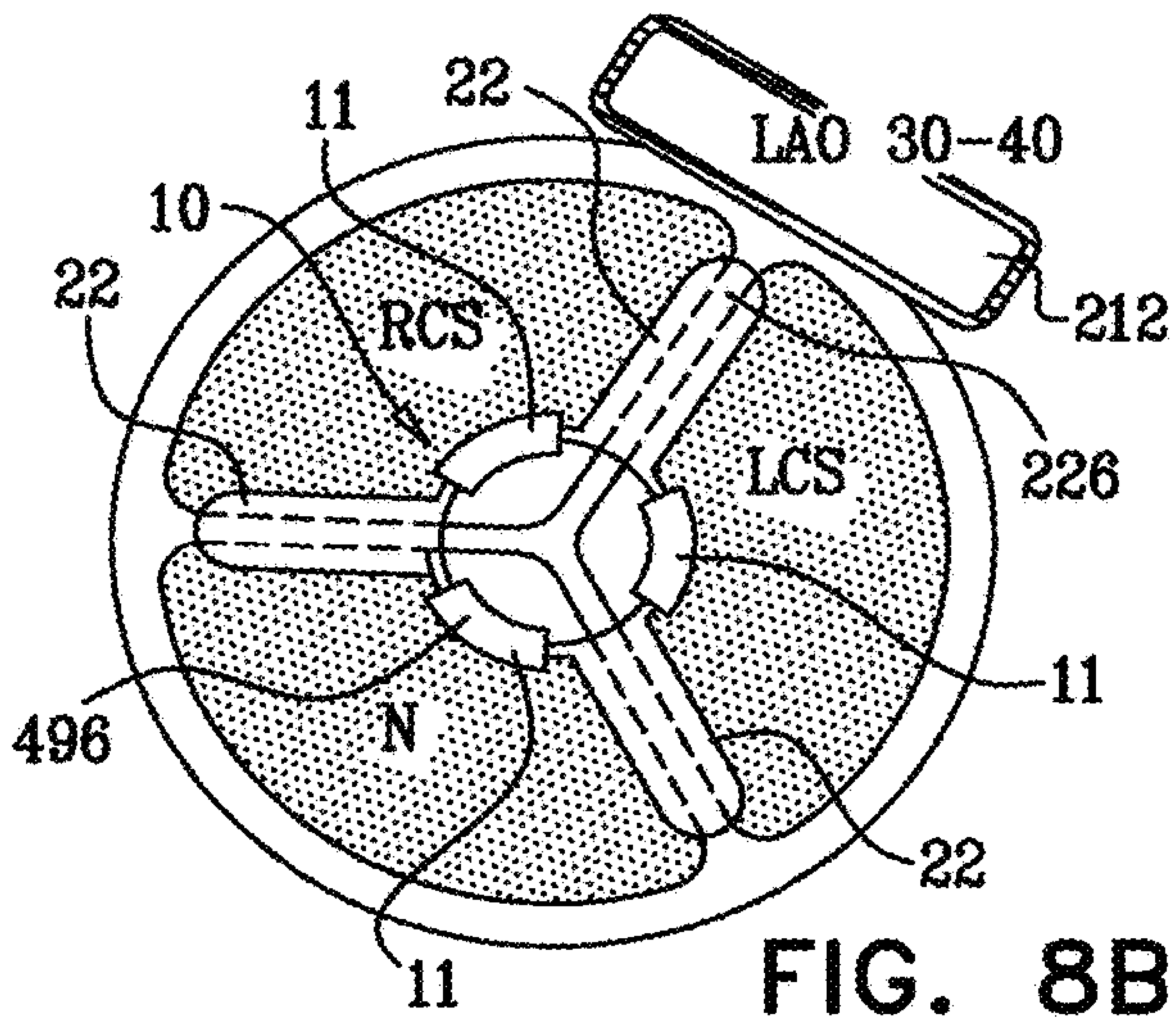


FIG. 8B

FIG. 9

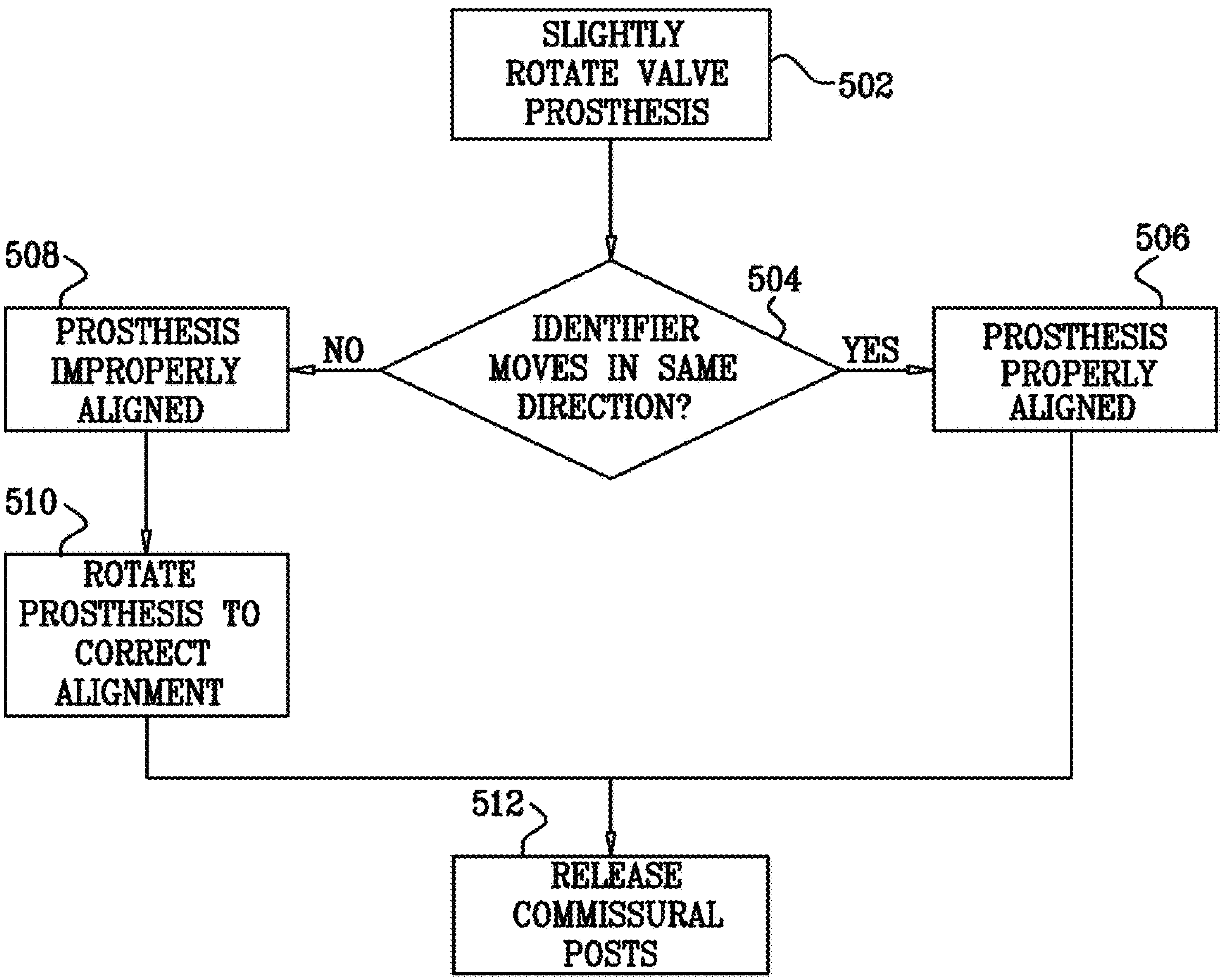


FIG. 10A

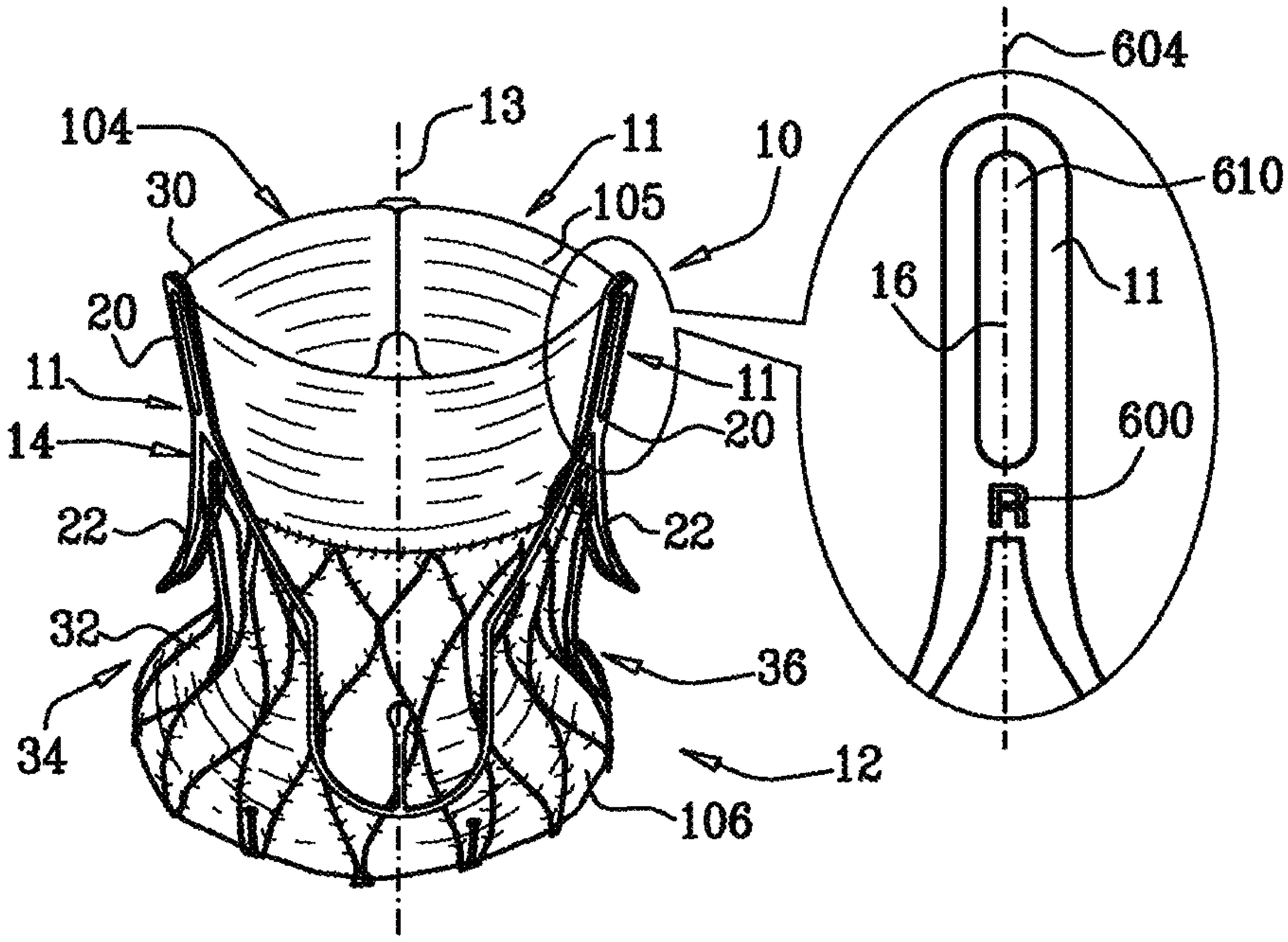
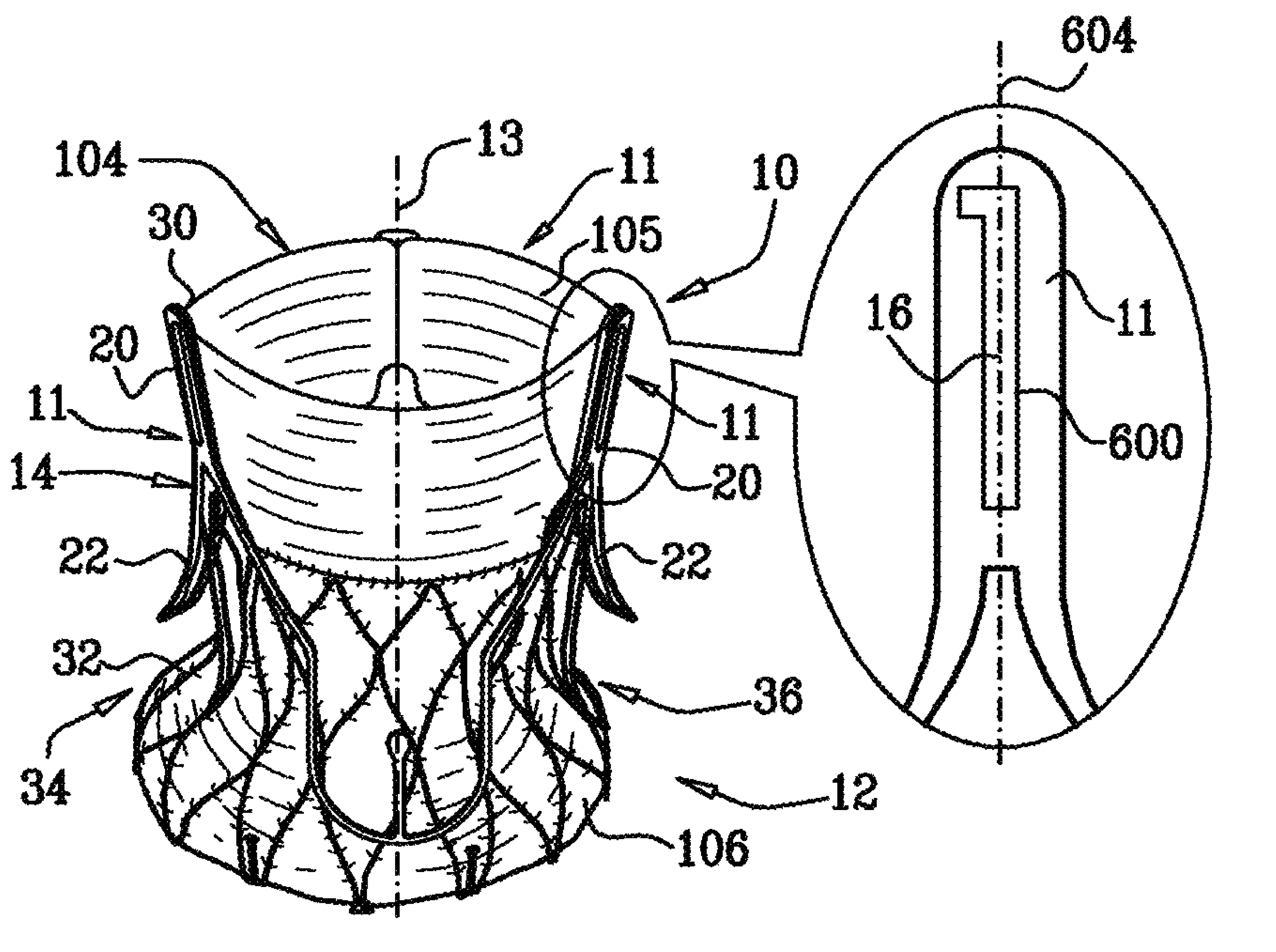


FIG. 10B



PROSTHETIC HEART VALVE HAVING IDENTIFIERS FOR AIDING IN RADIOGRAPHIC POSITIONING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of and claims priority to U.S. patent application Ser. No. 14/641,545, filed Mar. 9, 2015, now allowed, which is a Division of and claims priority to U.S. patent application Ser. No. 12/559,945, filed Sep. 15, 2009, now U.S. Pat. No. 8,998,981, which claims the benefit under 35 U.S.C. § 119(c) of U.S. Patent Application No. 61/192,201, filed Sep. 15, 2008, which are incorporated by references in their entirety.

FIELD OF THE INVENTION

The present invention relates generally to prosthetic heart valves, and specifically to techniques for accurately positioning such valves during implantation procedures.

BACKGROUND

Aortic valve replacement in patients with severe valve disease is a common surgical procedure. The replacement is conventionally performed by open heart surgery, in which the heart is usually arrested and the patient is placed on a heart bypass machine. In recent years, prosthetic heart valves have been developed which are implanted using minimally invasive procedures such as transapical or percutaneous approaches. These methods involve compressing the prosthesis radially to reduce its diameter, inserting the prosthesis into a delivery tool, such as a catheter, and advancing the delivery tool to the correct anatomical position in the heart. Once properly positioned, the prosthesis is deployed by radial expansion within the native valve annulus.

While these techniques are substantially less invasive than open heart surgery, the lack of line-of-sight visualization of the prosthesis and the native valve presents challenges, because the physician cannot see the actual orientation of the prosthesis during the implantation procedure. Correct positioning of the prostheses is achieved using radiographic imaging, which yields a two-dimensional image of the viewed area. The physician must interpret the image correctly in order to properly place the prostheses in the desired position. Failure to properly position the prostheses sometimes leads to device migration or to improper functioning. Proper device placement using radiographic imaging is thus critical to the success of the implantation.

PCT Publication WO 05/002466 to Schwammenthal et al., which is assigned to the assignee of the present application and is incorporated herein by reference, describes prosthetic devices for treating aortic stenosis.

PCT Publication WO 06/070372 to Schwammenthal et al., which is assigned to the assignee of the present application and is incorporated herein by reference, describes a prosthetic device having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define a fluid inlet and a diverging section, distal to the fluid inlet.

US Patent Application Publication 2006/0149360 to Schwammenthal et al., which is assigned to the assignee of the present application and is incorporated herein by reference, describes a prosthetic device including a valve-orifice attachment member attachable to a valve in a blood vessel and including a fluid inlet, and a diverging member that extends from the fluid inlet, the diverging member including a proximal end near the fluid inlet and a distal end distanced from the proximal end. A distal portion of the diverging member has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof.

US Patent Application Publication 2005/0197695 to Stacchino et al., describes a cardiac-valve prosthesis adapted for percutaneous implantation. The prosthesis includes an armature adapted for deployment in a radially expanded implantation position, the armature including a support portion and an anchor portion, which are substantially axially coextensive with respect to one another. A set of leaflets is coupled to the support portion. The leaflets can be deployed with the armature in the implantation position. The leaflets define, in the implantation position, a flow duct that is selectably obstructable. The anchor portion can be deployed to enable anchorage of the cardiac-valve prosthesis at an implantation site.

The following patents and patent application publications, are set forth as background:

U.S. Pat. No. 6,312,465 to Griffin et al.
U.S. Pat. No. 5,908,451 to Yeo
U.S. Pat. No. 5,344,442 to Deac
U.S. Pat. No. 5,354,330 to Hanson
US Patent Application Publication 2004/0260389 to Case et al.
U.S. Pat. No. 6,730,118 to Spencer et al.
U.S. Pat. No. 7,018,406 to Seguin et al.
U.S. Pat. No. 7,018,408 to Bailey et al.
U.S. Pat. No. 6,458,153 and US Patent Application Publication 2003/0023300 to Bailey et al.
US Patent Application Publication 2004/0186563 to Lobbi
US Patent Application Publication 2003/0130729 to Paniagua et al.
US Patent Application Publication 2004/0236411 to Sarac et al.
US Patent Application Publication 2005/0075720 to Nguyen et al.
US Patent Application Publication 2006/0058872 to Salahieh et al.
US Patent Application Publication 2005/0137686 Salahieh et al.
US Patent Application Publication 2005/0137690 to Salahieh et al.
US Patent Application Publication 2005/0137691 to Salahieh et al.
US Patent Application. Publication 2005/0143809 to Salahieh et al.
US Patent Application Publication 2005/0182483 to Osborne et al.
US Patent Application Publication 2005/0137695 to Salahieh et al.
US Patent Application Publication 2005/0240200 to Bergheim
US Patent Application Publication 2006/0025857 to Bergheim et al.
US Patent Application Publication 2006/0025855 to Lashinski et al.
US Patent Application Publication 2006/0047338 to Jenson et al.
US Patent Application Publication 2006/0052867 to Revuelta et al.
US Patent Application Publication 2006/0074485 to Realyvasquez
US Patent Application Publication 2006/0259136 to Nguyen et al.

U.S. Pat. No. 7,137,184 to Schreck
U.S. Pat. No. 6,296,662 to Caffey

SUMMARY

In some embodiments of the present invention, a prosthetic heart valve prosthesis comprises three commissural posts to which are coupled a prosthetic valve. The commissural posts are shaped so as define therethrough respective openings that serve as radiographic identifiers during an implantation procedure. During the procedure, the valve prosthesis, including the commissural posts, is initially collapsed within a delivery tube. Before expanding the valve prosthesis, a physician uses radiographic imaging, such as x-ray fluoroscopy, to provide visual feedback that aids the physician in rotationally aligning the commissural posts with respective native commissures of a native semilunar valve. The identifiers strongly contrast with the rest of the commissural posts and the valve prosthesis, which comprise a radiopaque material. Without such identifiers, it is generally difficult to three-dimensionally visually distinguish the commissural posts from one another and from the rest of the valve prosthesis, because the radiographic imaging produces a two-dimensional representation of the three-dimensional valve prosthesis. When the valve prosthesis is in a collapsed state, the elements thereof overlap in a two-dimensional image and are generally indistinguishable.

In some embodiments of the present invention, the physician selects one of the commissural posts having a radiographic identifier, and attempts to rotationally align the selected post with one of the native commissures, such as the commissure between the left and right coronary sinuses. Because the radiographic image is two-dimensional, all of the posts appear in the image as though they are in the same plane. The physician thus cannot distinguish between two possible rotational positions of the posts: (1) the desired rotational position, in which the selected post faces the desired native commissure, and (2) a rotational position 180 degrees from the desired rotational position, in which the selected post faces the side of the native valve opposite the desired native commissure. For example, if the desired native commissure is the commissure between the left and right coronary sinuses, in position (2) the post is rotationally aligned with the noncoronary sinus, although this undesired rotation is not apparent in the radiographic image.

To ascertain whether the posts are in rotational Position (1) or (2), the physician slightly rotates the valve prosthesis. If the radiographic identifier on the selected post appears to move in the radiographic image in the same direction as the rotation, the selected post is correctly rotationally aligned in the desired position (1). If, on the other hand, the radiographic identifier appears to move in the direction opposite the direction of rotation, the selected post is incorrectly rotationally aligned in position (2). To correct the alignment, the physician may rotate the valve prosthesis approximately 60 degrees in either direction, thereby ensuring that one of the two other posts is now rotationally aligned in position (1). (The valve prosthesis typically has three-fold rotational symmetry, such that rotation of 60 degrees is sufficient to properly align one of the posts with the selected native commissure, and the prosthesis need not be rotated a full 180 degrees.) In these embodiments, the openings through the posts that define the radiographic identifiers may assume any convenient shape, such as a slit.

In some embodiments of the present invention, the openings that define the radiographic identifiers are shaped to be reflection-asymmetric along respective post axes that are generally parallel with a central longitudinal axis of the prosthesis when the posts assume their collapsed position. For example, the identifiers may be shaped as one or more reflection-asymmetric characters, such as numbers or letters of the alphabet, e.g., B, C, D, E, etc. The physician can thus readily identify the true orientation of the selected post that appears to be rotationally aligned with the selected native commissure. If the identifier on the selected post appears in the correct left-right orientation, the selected post is aligned in the desired position (1). If, on the other hand, the identifier appears as the mirror image of its correct left-right orientation, the selected post is incorrectly rotationally aligned in position (2). To correct the alignment, the physician may rotate the valve prosthesis approximately 60 degrees in either direction, thereby ensuring that one of the two other posts is now rotationally aligned in position (1).

There is therefore provided, in accordance with an embodiment of the present invention, apparatus including a valve prosthesis, which includes a prosthetic heart valve, and three or more commissural posts, to which the prosthetic heart valve is coupled. The posts are arranged circumferentially around a central longitudinal axis of the valve prosthesis, and are configured to assume a collapsed position prior to implantation of the prosthesis, and an expanded position upon the implantation of the prosthesis. One or more of the commissural posts are provided with respective radiographic identifiers that are shaped to be reflection-asymmetric about respective post axes that are generally parallel with the central longitudinal axis when the posts assume the collapsed position.

For some applications, the radiographic identifiers have the shape of one or more reflection-asymmetric characters.

In an embodiment, the one or more of the commissural posts are shaped to define respective openings therethrough which define the respective radiographic identifiers. Alternatively, the radiographic identifiers include a material having a first radiopacity that is different from a second radiopacity of the commissural posts, which material is coupled to the one or more of the commissural posts.

For some applications, the valve prosthesis includes exactly three commissural posts.

There is further provided, in accordance with an embodiment of the present invention, a method including:

providing a valve prosthesis that includes a prosthetic heart valve, and three or more commissural posts, to which the prosthetic heart valve is coupled, which posts are arranged circumferentially around a central longitudinal axis of the valve prosthesis, and are configured to assume a collapsed position prior to implantation of the prosthesis, and an expanded position upon the implantation of the prosthesis, and at least one of which commissural posts is provided with a radiographic identifier;

while the posts assume the collapsed position, placing, via a blood vessel of the subject, the valve prosthesis at least partially in a heart of a subject in a vicinity of a native heart valve having native commissures;

generating a fluoroscopic image of the native commissures and valve prosthesis; and

rotationally aligning the at least one of the commissural posts with one of the native commissures using the radiographic identifier visible in the image.

In an embodiment, rotationally aligning includes rotating the valve prosthesis; observing whether the at least one of the commissural posts appears to move in the image in the same direction that the valve prosthesis is rotated, or in an opposite direction; and, if the at least one of the commissural posts appears to move in the image. in the opposite direction, rotating the valve prosthesis to correct. a rotational alignment of the valve prosthesis.

For some applications, the valve prosthesis includes exactly three commissural posts, and is configured to have three-fold rotational symmetry, and rotating the valve prosthesis to correct the rotational alignment includes rotating the valve prosthesis approximately 60 degrees.

In an embodiment, the radiographic identifier is shaped to be reflection-asymmetric about a post axis of the at least one of the commissural posts, which axis is generally parallel with the central longitudinal axis when the posts assume the collapsed position. For some applications, the radiographic identifier has the shape of a reflection-asymmetric character.

For some applications, rotationally aligning includes observing in the image whether the radiographic identifier appears in a correct left-right orientation, and, if the radiographic identifier does not appear in the correct left-right orientation, rotating the valve prosthesis to correct a rotational alignment of the valve prosthesis. For some applications, the valve prosthesis includes exactly three commissural posts, and is configured to have three-fold rotational symmetry, and rotating the valve prosthesis to correct the rotational alignment includes rotating the valve prosthesis approximately 60 degrees.

In an embodiment, the at least one of the commissural posts is shaped to define an opening therethrough which defines the radiographic identifier. Alternatively, the radiographic identifier includes a material having a first radiopacity that is different from a second radiopacity of the at least one of the commissural posts, which material is coupled to the at least one of the commissural posts.

For some applications, the one of the native commissures is a native commissure (C_{RL}) between a left coronary sinus and a right coronary sinus, and rotationally aligning includes rotationally aligned the one of the commissural posts with the C_{RL}.

There is still further provided, in accordance with an embodiment of the present invention, a method including:

providing a valve prosthesis that includes a prosthetic heart valve, and three or more commissural posts, to which the prosthetic heart valve is coupled, which posts are arranged circumferentially around a central longitudinal axis of the valve prosthesis, and are configured to assume a collapsed position prior to implantation of the prosthesis, and an expanded position upon the implantation of the prosthesis;

while the posts assume the collapsed position, placing, via a blood vessel of the subject, the valve prosthesis at least partially in a heart of a subject in a vicinity of a native heart valve having native commissures;

generating a fluoroscopic image of the native commissures and valve prosthesis; and

rotationally aligning the at least one of the commissural posts with one of the native commissures by:

rotating the valve prosthesis,

observing whether the at least one of the commissural posts appears to move in the image in the same direction that the valve prosthesis is rotated, or in an opposite direction, and

if the at least one of the commissural posts appears to move in the image in the opposite direction, rotating the valve prosthesis to correct a rotational alignment of the valve prosthesis.

For some applications, the valve prosthesis includes exactly three commissural posts, and is configured to have three-fold rotational symmetry, and rotating the valve prosthesis to correct the rotational alignment includes rotating the valve prosthesis approximately 60 degrees.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus including a valve prosthesis, which includes:

a prosthetic heart valve;

a support structure, which includes a first material having a first radiopacity; and

one or more radiographic identifiers, which include a second material having a second radiopacity different from the first radiopacity, and which are coupled to the support structure at respective locations.

In an embodiment, the radiographic identifiers are shaped to be reflection-asymmetric about respective identifier axes that are generally parallel with a central longitudinal axis of the valve prosthesis.

For some applications, the identifiers are arranged circumferentially around a central longitudinal axis of the valve prosthesis.

For some applications, the support structure is shaped so as to define a bulging proximal skirt, and the identifiers are coupled to the skirt.

For some applications, the support structure includes three or more commissural posts, to which the prosthetic heart valve is coupled, which posts are arranged circumferentially around a central longitudinal axis of the valve prosthesis, the locations at which the identifiers are coupled to the support structure are not on the posts, and the locations are radially aligned with the posts.

For some applications, the support structure includes three or more commissural posts, to which the prosthetic heart valve is coupled, which posts are arranged circumferentially around a central longitudinal axis of the valve prosthesis, and the locations at which the identifiers are coupled to the support structure are on the posts.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of a fully-assembled valve prosthesis, in accordance with an embodiment of the present invention;

FIGS. **2**A and **2**B are schematic illustrations of a collapsible outer support structure and a collapsible inner support structure, respectively, prior to assembly together into the valve prosthesis of FIG. **1**, in accordance with an embodiment of the present invention;

FIG. **3** is a schematic illustration of a subject undergoing a transapical or percutaneous valve replacement procedure, in accordance with an embodiment of the present invention;

FIG. **4** shows an exemplary fluoroscopic view generated with a fluoroscopic system during a valve replacement procedure, in accordance with an embodiment of the present invention;

FIG. **5** shows an exemplary ultrasound view generated with an ultrasound probe during a valve replacement procedure, in accordance with an embodiment of the present invention;

FIGS. **6**A and **6**B are schematic and fluoroscopic views, respectively, of the valve prosthesis of FIG. **1** in a collapsed position in a catheter, in accordance with an embodiment of the present invention;

FIGS. **7**A and **7**B are schematic illustrations of the valve prosthesis of FIG. **1** in situ upon completion of transapical and retrograde transaortic implantation procedures, respectively, in accordance with respective embodiments of the present invention;

FIGS. **7**C-**7**E are schematic illustrations of an implantation procedure of an alternative configuration of the valve prosthesis of FIG. **1**, in accordance with an embodiment of the present invention;

FIGS. **8**A-B are schematic illustrations of the valve prosthesis of FIG. **1** positioned within the aortic root, in accordance with an embodiment of the present invention;

FIG. **9** is a flow chart that schematically illustrates a method for ascertaining whether the valve prosthesis of FIG. **1** or FIGS. **7**C-E are properly rotationally aligned with the native commissures, in accordance with an embodiment of the present invention and

FIGS. **10**A and **10**B are schematic illustrations of reflection-asymmetric radiographic identifiers on commissural posts of the valve prosthesis of FIG. **1** or FIGS. **7**C-E, in accordance with respective embodiments of the present invention.

DETAILED DESCRIPTION

FIG. **1** is a schematic illustration of a fully-assembled valve prosthesis **10**, in accordance with an embodiment of the present invention. Typically, valve prosthesis **10** comprises exactly three commissural posts **11**, arranged circumferentially around a central longitudinal axis **13** of valve prosthesis **10**. Valve prosthesis **10** further comprises a prosthetic distal valve **104** coupled to couple to commissural posts **11**. Valve **104** typically comprises a pliant material **105**. Pliant material **105** of valve **104** is configured to collapse inwardly (i.e., towards central longitudinal axis **13**) during diastole, in order to inhibit retrograde blood flow, and to open outwardly during systole, to allow blood flow through the prosthesis. For some applications, valve prosthesis **10** comprises a collapsible inner support structure **12** that serves as a proximal fixation member, and a collapsible outer support structure **14** that serves as a distal fixation member.

One or more (e.g., all) of commissural posts **11** are shaped so as define therethrough respective openings **16** that serve as radiographic identifiers during an implantation procedure, as described herein below with reference to FIGS. **3**-**8**B. The openings may assume any convenient, shape, for example, slits, as shown in FIGS. **1**, **2**A-B, and **6**A-B. In some embodiments, the openings are shaped to be reflection-asymmetric along respective post axes generally parallel with central longitudinal axis **13** of prosthesis **10** when the posts assume their collapsed position, as described herein below with reference to FIGS. **10**A-B. For some applications, in addition to serving as the radiographic identifiers, openings **16** are used for coupling valve **104** to support structures **12** and **14**. Although pliant material **105** of valve **104** at least partially fills openings **16**, the material is substantially more radiolucent than commissural posts **11**, and thus does not reduce the radiographic visibility of the radiographic identifiers. Alternatively, one or more of posts **11** do not necessarily define openings **16**, and the one or more posts instead comprise radiographic identifiers comprising a material having a radiopacity different from (greater or less than) the radiopacity of posts **11**, such as gold or tantalum.

Valve prosthesis **10** is configured to be placed in a native diseased valve of a subject, such as a native stenotic aortic or pulmonary valve, using a minimally-invasive approach, such as a beating heart transapical procedure, such as described herein below with reference to FIG. **7**A, or a retrograde transaortic procedure, such as described herein below with reference to FIG. **7**B. As used in the present application, including in the claims, a "native semilunar valve" is to be understood as including: (a) native semilunar valves that include their native leaflets, and (b) native semilunar valves, the native leaflets of which have been surgically excised or are otherwise absent.

Reference is made to FIG. **2**A, which is a schematic illustration of collapsible outer support structure **14** prior to assembly with inner support structure **12**, in accordance with an embodiment of the present invention. In this embodiment, outer support structure **14** is shaped so as to define a plurality of distal diverging strut supports **20**, from which a plurality of proximal engagement arms **22** extend radially outward in a proximal direction. Engagement arms **22** are typically configured to be at least partially disposed within aortic sinuses of the subject, and, for some applications, to engage and/or rest against floors of the aortic sinuses, and to apply an axial force directed toward a left ventricle of the subject. Outer support structure **14** comprises a suitable material that allows mechanical deformations associated with crimping and expansion of valve prosthesis **10**, such as, but not limited to, nitinol or a stainless steel alloy (e.g., AISI **316**).

Reference is made to FIG. **23**, which is a schematic illustration of collapsible inner support structure **12** prior to assembly with outer support structure **14**, in accordance with an embodiment of the present invention. For some applications, inner support structure **12** is shaped so as to define a plurality of distal diverging inner struts **30**, and a bulging proximal skirt **32** that extends from the struts. A proximal portion **34** of proximal skirt **32** is configured to engage a left ventricular outflow tract (LVOT) of the subject and/or periannular tissue at the top of the left ventricle. A relatively narrow throat section **36** of proximal skirt **32** is configured to be positioned at a valvular annulus of the subject, and to engage the native valve leaflets. Inner support structure **12** comprises, for example, nitinol, a stainless steel alloy, another metal, or another biocompatible material.

Reference is again made to FIG. **1**. Inner and outer support structures **12** and **14** are assembled together by placing outer support structure **14** over inner support structure **12**, such that cuter strut supports **20** are aligned with, and typically support, respective inner struts **30**, and engagement arms **22** are placed over a portion of proximal skirt **32**. Inner struts **30** and outer strut supports **20** together define commissural posts **11**.

Although exactly three commissural posts **11** are shown in the figures, for some applications valve prosthesis **10** comprises fewer or more posts **11**, such as two posts **11**, or four or more posts **11**.

Typically, valve prosthesis **10** further comprises a graft covering **106** which is coupled to proximal skirt **32**, such as by sewing the covering within the skirt (configuration shown in FIG. **1**) or around the skirt (configuration not shown). Inner support structure **12** thus defines a central structured body for flow passage that proximally terminates in a flared inlet (proximal skirt **32**) that is configured to be seated within an LVOT immediately below an aortic annulus/aortic valve. For some applications, graft covering **106** is coupled at one or more sites to pliant material **105**.

In an embodiment of the present invention, a portion valve prosthesis **10** other than commissural posts **11**, e.g., proximal skirt. **32**, is shaped so as to define openings **16** that serve as radiographic identifiers. Alternatively or additionally, the commissural posts or this other portion of the prosthesis comprise radiographic identifiers comprising a material having a radiopacity different from (greater or less than) the radiopacity of other portions of the prosthesis. For some applications, the radiographic identifiers are radially aligned with commissural posts **11**.

FIG. **3** is a schematic illustration of a subject **200** undergoing a transapical or percutaneous valve replacement procedure, in accordance with an embodiment of the present invention. A fluoroscopy system **210** comprises a fluoroscopy source **213**, a fluoroscopy detector **212**, and a monitor **214**. Fluoroscopy source **213** is positioned over subject **200** so as to obtain a left anterior oblique (LAO) projection of between **30** and **45**, such as between 30 and 40, degrees with a 30-degree cranial tilt (for orthogonal projection of the annulus). Typically, imaging is enhanced using an ultrasound probe **216**.

FIG. **4** shows an exemplary fluoroscopic view **220** generated with fluoroscopic system **210** during a valve replacement procedure, in accordance with an embodiment of the present invention. In the view, a right coronary sinus (RCS) **222** and a left coronary sinus (LCS) **224** are visible, as are the respective coronary arteries that originate from the sinuses. The view also shows a commissure **226** between the right and left sinuses (C_{RL}). RCS **222**, LCS **224**, and C_{RL} **226** serve as clear anatomical landmarks during the replacement procedure, enabling the physician to readily ascertain the layout of the aortic root.

FIG. **5** shows an exemplary ultrasound view **230** generated with ultrasound probe **216** during a valve replacement procedure, in accordance with an embodiment of the present invention. In the view, the RCS, LCS, and non-coronary sinus (N) are visible. The orientation of view **230** can be seen with respect to a sternum **232** and a spine **234**, as well as with respect to fluoroscopy detector **212**.

FIGS. **6**A and **6**B are schematic and fluoroscopic views, respectively, of valve prosthesis **10** in a collapsed position in a catheter **300**, in accordance with an embodiment of the present invention. In this embodiment, openings **16** are shaped as slits. As can be seen in FIG. **613**, these slits are clearly visible with fluoroscopy.

Reference is made to FIGS. **7**A and **7**B, which are schematic illustrations of valve prosthesis **10** in situ upon completion of transapical and retrograde transaortic implantation procedures, respectively, in accordance with respective embodiments of the present invention.

In the transapical procedure, as shown in FIG. **7**A, an introducer overtube or trocar **150** is inserted into a left ventricular apex **156** using a Seldinger technique. Through this trocar, a delivery catheter (not shown in the figure) onto which collapsed valve prosthesis **10** is mounted, is advanced into a left ventricle **357** where its motion is terminated, or through left ventricle **357** until the distal end of a dilator (not shown) passes native aortic valve leaflets **358**. For example, apex **356** may be punctured using a standard Seldinger technique, and a guidewire may be advanced into an ascending aorta **360**. Optionally, a native aortic valve **340** is partially dilated to about 15-20 mm (e.g., about 16 mm), typically using a standard valvuloplasty balloon catheter. (In contrast, full dilation would be achieved utilizing dilation of 20 mm or more.) Overtube or trocar **350** is advanced into the ascending aorta. Overtube or trocar **350** is pushed beyond aortic valve **340** such that the distal end of overtube or trocar **350** is located above the highest point of native aortic valve **340**. The dilator is removed while overtube or trocar **350** remains in place with its distal end located above aortic valve **340**. Alternatively, the procedure may be modified so that overtube or trocar **350** is placed within left ventricle **350** and remains within the left ventricle throughout the entire implantation procedure. Valve prosthesis **10** is advanced through the distal end of overtube or trocar **350** into ascending aorta. **360** distal to native leaflets **358**.

Valve prosthesis **10**, typically while still within the catheter, is rotated to align arms **22** with aortic sinuses **364**, as described herein below with reference to FIGS. **8**A-B or FIGS. **10**A-B. After the prosthesis is properly rotationally aligned, withdrawal of the catheter causes engagement arms **22** to flare out laterally to an angle which is typically predetermined by design, and to open in an upstream direction. Gentle withdrawal of the delivery catheter, onto which prosthesis **10** with flared-out arms **22** is mounted, causes the arms to slide into aortic sinuses **364**. Release of the device from the delivery catheter causes a lower inflow portion of prosthesis **10** to unfold and press against the upstream side of native leaflets **358**, thereby engaging with the upstream fixation arms in the aortic sinuses. The upstream fixation arms serve as counterparts to the lower inflow portion of the prosthesis in a mechanism that locks the native leaflets and the surrounding periannular tissue for fixation.

For some applications, prosthesis **10** is implanted using techniques described with reference to FIGS. **5**A-C in U.S. application Ser. No. 12/050,628, filed Mar. 18, 2008, entitled, "Valve suturing and implantation procedures," which is incorporated herein by reference.

In the retrograde transaortic procedure, as shown in FIG. **7**B, valve prosthesis **10** is positioned in a retrograde delivery catheter **450**. A retrograde delivery catheter tube **451** of catheter **450** holds engagement arms **22**, and a delivery catheter cap **452** holds proximal skirt **32** (not shown). A guidewire **490** is transaortically inserted into left ventricle **357**. Optionally, stenotic aortic valve **340** is partially dilated to about 15-20 mm (e.g., about 16 mm), typically using a standard valvuloplasty balloon catheter. Retrograde delivery catheter **450** is advanced over guidewire **490** into ascending aorta **360** towards native aortic valve **340**. Retrograde delivery catheter **450** is advanced over guidewire **490** until delivery catheter cap **452** passes through native aortic valve **340** partially into left ventricle **357**.

Valve prosthesis **10**, typically while still within the catheter, is rotated to align arms **22** with aortic sinuses **364**, as described herein below with reference to FIGS. **8**A-B or FIGS. **1**A-B. Retrograde delivery catheter tube **451** is pulled back (in the direction indicated schematically by an arrow **455**), while a device stopper (not shown) prevents valve prosthesis **10** within tube **451** from being pulled back with tube **451**, so that engagement arms **22** are released and flare out laterally into the sinuses. At this stage of the implantation procedure, proximal skirt **32** of prosthesis **10** remains in delivery catheter cap **452**.

Delivery catheter cap **452** is pushed in the direction of the apex of the heart, using a retrograde delivery catheter cap shaft (not shown) that passes through tube **451** and prosthesis **10**. This advancing of cap **452** frees proximal skirt **32** to snap or spring open, and engage the inner surface of the LVOT. Retrograde delivery catheter tube **451** is further pulled back until the rest of valve prosthesis **10** is released from the tube. Retrograde delivery catheter tube **451** is again advanced over the shaft toward the apex of the heart, until tube **451** rejoins cap **452**. Retrograde delivery catheter **450** and guidewire **490** are withdrawn from left ventricle **357**, and then from ascending aorta **360**, leaving prosthesis **10** in place.

For some applications, prosthesis **10** is implanted using techniques described with reference to FIGS. 9A-G in above-mentioned U.S. application Ser. No. 12/050,628.

Reference is made to FIGS. 7C-7E, which are schematic illustrations of an implantation procedure of an alternative configuration of valve prosthesis **10**, in accordance with an embodiment of the present invention. In this configuration, valve prosthesis **10** does not comprise proximal engagement arms **22**. Even without these arms, which rest in the sinus floors and thus may aid in properly rotationally aligning the prosthesis, the techniques described herein achieve proper alignment of the prosthesis. For some applications, valve prosthesis **10** is configured as described in a US provisional patent application filed on even date herewith, entitled, "Prosthetic heart valve for transfemoral delivery," which is assigned to the assignee of the present application and is incorporated herein by reference.

FIG. **7**C shows valve prosthesis **10** positioned in retrograde delivery catheter **450**, which is advanced into left ventricle **357** over guidewire **490**. Valve prosthesis **10**, typically while still within the catheter, is rotated to align commissural posts **11** with the native commissures, as described herein below with reference to FIGS. **8**A-B or FIGS. **10**A-B. After the prosthesis is properly rotationally aligned, withdrawal of the catheter causes expansion of the frame of prosthesis, as shown in FIG. **7**D. FIG. **7**E shows this configuration of prosthesis **10** positioned within the aortic root (viewed from the aorta). The frame of the prosthesis is shaped so as to define distal support members **492**, which extend in a downstream direction (i.e., they do not extend into the floors of the aortic sinuses). Distal support elements **492** are configured to rest against the downstream portion of the aortic sinuses upon implantation of valve prosthesis **10**, so as to provide support against tilting of the prosthesis with respect to a central longitudinal axis of the prosthesis. As can be seen in FIG. **7**E, commissural posts **11** of the valve prosthesis are rotationally aligned with native commissures **494**.

Reference is made to FIGS. **8**A-B, which are schematic illustrations of valve prosthesis **10** positioned within the aortic root (viewed from the aorta), in accordance with an embodiment of the present invention. As described above with reference to FIGS. **7**A-B, during an implantation procedure, a delivery catheter is inserted into an overtube and advanced until the distal end of commissural posts **11** arrive near the end of the overtube.

For configurations of valve prosthesis **10** that include proximal engagement arms **22**, the arms are still within the catheter. To properly rotationally align pests with the native commissures, the physician rotates valve prosthesis **10** under fluoroscopy until one **496** of commissural posts **11** is aligned with one of the native commissures, such as commissure **226** between the right and left sinuses (C_{RL}). In an attempt to achieve such a rotational position, the physician rotates the prosthesis until one of openings **16** that serve as radiographic identifiers is centered from the viewpoint of the fluoroscopic LAO projection such as shown in FIG. **6**B (openings **16** are not visible from the view of FIGS. **8**A-B). The other two commissural posts **11** flank the centered post.

At this stage of the procedure, because the radiographic image is two-dimensional and all of the posts appear in the image as though they are in the same plane, it is difficult for the physician to ascertain whether commissural post **496** selected for alignment is:

(1) in the desired rotational position, closer to fluoroscopy detector **212** (FIG. **3**) than are the other two commissures, and thus properly aligned with the C_{RL} **226**, as shown in FIG. **8**A; or

(2) farther away from the fluoroscopy detector than are the other two posts, rotated 180 degrees from the desired rotational position, as shown in FIG. **8**B. In this rotational orientation, centered post **496** projects itself onto C_{RL} **226**, but actually faces the noncoronary sinus (N) away from the fluoroscopy detector, such that valve prosthesis **10** is misaligned by 60 degrees (because the prosthesis typically has three-fold rotational symmetry).

Reference is made to FIG. **9**, which is a flow chart that schematically illustrates a method **500** for ascertaining whether the posts are in the first or second possible rotational position, in accordance with an embodiment of the present invention. At an initial rotation step **502**, the physician slightly rotates valve prosthesis **10**. At an apparent rotation check step **504**, the physician ascertains whether the radiographic identifier on the selected post appears to move in the radiographic image in the same direction as the rotation. If the identifier appears to move in the same direction as the rotation, the physician ascertains that the selected post is correctly rotationally aligned in the desired position (1) (after the physician slightly rotates the prosthesis in the opposite direction to return it to its initial position), at a proper alignment ascertainment step **506**. If, on the other hand, the radiographic identifier appears to move in the direction opposite the direction of rotation, the physician ascertains that the selected post is incorrectly rotationally aligned in position (2), at an improper alignment ascertainment step **508**. To correct the alignment, the physician rotates the valve prosthesis approximately 60 degrees in either direction, thereby ensuring that one of the two other posts is now rotationally aligned in position (1), at an alignment correction step **510**. (The valve prosthesis typically has three-fold rotational symmetry, such that rotation of 60 degrees is sufficient to properly align one of the posts with the selected native commissure, and the prosthesis need not be rotated a full 180 degrees.) For example, assume that at initial rotation step **502** the physician rotates the prosthesis clockwise, as viewed from the aorta. If the valve prosthesis is properly aligned, the radiographic identifier on the selected post appears to move toward the LCS at apparent rotation check step **504**. Once the valve prosthesis is properly aligned, commissural posts **11** are released from the catheter, as well as proximal engagement arms **22**, for configurations of the prosthesis that include such arms, at a commissural post release step **512**. In these embodiments, openings **16** through posts **11** that define the radiographic identifiers may assume any convenient shape, such as a slit.

In an embodiment of the present invention, this technique for rotationally aligning posts **11** with the native commissures is used for aligning a valve prosthesis that does not include radiographic identifiers. Instead of using such identifiers, the physician observes elements of the prosthesis that are discernible in the radiographic images, such as posts **11**.

FIGS. **10**A and **10**B are schematic illustrations of reflection-asymmetric radiographic identifiers **600** on commissural posts **11**, in accordance with respective embodiments of the present invention. Identifiers **600** may be used with both the configuration of valve prosthesis **10** described hereinabove with reference to FIG. **1**, and that described hereinabove with reference to FIGS. **7**C-E. Openings **16** that define radiographic identifiers **600** are shaped to be reflection-asymmetric along respective, post axes **604** that are generally parallel central longitudinal axis **13** of prosthesis **10** when the posts assume their collapsed position. For example, as shown in FIG. **10**A, identifiers **600** may be shaped as one or more reflection-asymmetric letters of the alphabet, such as B, C, D, E, etc., or numbers. Alternatively, the identifier may be shaped as any reflection-symmetric symbol, such as the inverted elongated L shown in FIG. **10**B. The physician can thus readily identify the true orientation of the selected post that appears to be rotationally aligned with the selected native commissure. If the identifier on the selected post appears in the correct left-right orientation, the selected post is aligned in the desired position (1), as described hereinabove with reference to FIGS. **8**A-B. If, on the other hand, the identifier appears as the mirror image of its correct left-right orientation, the selected post is incorrectly rotationally aligned in position (2) as described hereinabove with reference to FIGS. **8**A-B. To correct the alignment, the physician rotates the valve prosthesis approximately 60 degrees in either direction, thereby ensuring that one of the two other posts is now rotationally aligned in position (1).

For some applications, such as shown in FIG. **10**A, at least one of commissural posts **11** is shaped so as to define both reflection-asymmetric radiographic identifier **600** and another reflection-symmetric shape **610**, such as a slit. For example, such a slit may have a mechanical purpose, such as coupling valve **104** to support structures **12** and **14**, as described hereinabove with reference to FIG. **1**. Alternatively, the physician may use reflection-symmetric shape **610** for rotational orientation as described hereinabove with reference to FIGS. **8**A-B in the event that reflection-asymmetric radiographic identifiers **600** are not be clearly visible in the radiographic image during a particular implantation procedure.

For some applications, reflection-asymmetric radiographic identifiers **600** are not defined by openings **16**, but instead comprise a material having a radiopacity different from (greater or less than) the radiopacity of other portions of the posts. For some applications, a portion of valve prosthesis **10** other than commissural posts **11** comprises radiographic identifiers **600** (whether defined by openings, or comprising a material having a different radiopacity).

For some applications, techniques described herein are performed in combination with techniques described in a US provisional patent application filed on even date herewith, entitled, "Prosthetic heart valve for transfemoral delivery," which is assigned to the assignee of the present application and is incorporated herein by reference.

The scope of the present invention includes embodiments described in the following applications, which are assigned to the assignee of the present application and are incorporated herein by reference. In an embodiment, techniques and apparatus described in one or more of the following applications are combined with techniques and apparatus described herein:

- U.S. patent application Ser. No. 11/024,908, filed Dec. 30, 2004, entitled, "Fluid flow prosthetic device," which issued as U.S. Pat. No. 7,201,772;
- International Patent Application PCT/IL2005/001399, filed Dec. 29, 2005, entitled, "Fluid flow prosthetic device," which published as PCT Publication WO 06/070372;
- International Patent Application PCT/IL2004/000601, filed Jul. 6, 2004, entitled, "Implantable prosthetic devices particularly for transarterial delivery in the treatment of aortic stenosis, and methods of implanting such devices," which published as PCT Publication WO 05/002466, and U.S. patent application Ser. No. 10/563,384, filed Apr. 20, 2006, in the national stage thereof, which published as US Patent Application Publication 2006/0259134;
- U.S. Provisional Application 60/845,728, filed Sep. 19, 2006, entitled, "Fixation member for valve";
- U.S. Provisional Application 60/852,435, filed Oct. 16, 2006, entitled, "Transapical delivery system with ventriculo-arterial overflow bypass";
- U.S. application Ser. No. 11/728,253, filed Mar. 23, 2007, entitled, "Valve prosthesis fixation techniques using sandwiching";
- International Patent Application PCT/IL2007/001237, filed Oct. 16, 2007, entitled, "Transapical delivery system with ventriculo-arterial overflow bypass," which published as POT Publication WO 2008/047354; and/or
- U.S. application Ser. No. 12/050,628, filed Mar. 18, 2008, entitled, "Valve suturing and implantation procedures."

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

What is claimed is:

1. A method comprising the steps of:

providing a valve prosthesis that includes a prosthetic heart valve, wherein the valve prosthesis has a collapsed configuration and an expanded configuration, and at least one radiographic identifier;

wherein the valve prosthesis is configured to have three-fold rotational symmetry;

while the valve prosthesis is in the collapsed configuration, placing, via a blood vessel of the subject, the valve prosthesis at least partially in a heart of a subject in a vicinity of a native heart valve having native commissures;

generating a fluoroscopic image of the native commissures and valve prosthesis; and

rotationally aligning the radiographic identifier visible in the image with at least one of the native commissures;

wherein rotationally aligning comprises:

rotating the valve prosthesis;

observing whether the radiographic identifier appears to move in the image in the same direction that the valve prosthesis is rotated, or in an opposite direction; and

if the radiographic identifier appears to move in the image in the opposite direction, rotating the valve prosthesis approximately 60 degrees to correct a rotational alignment of the valve prosthesis.

2. The method of claim **1**, wherein the valve prosthesis includes a plurality of commissural posts.

3. The method of claim **2**, wherein the valve prosthesis includes exactly three commissural posts.

4. The method of claim **2**, wherein the radiographic identifier is shaped to be reflection-asymmetric about a post axis of one of the plurality of commissure posts, which the post axis is generally parallel with a central longitudinal axis of the valve prosthesis when the plurality of commissure posts assume the collapsed configuration.

5. The method of claim **4**, wherein the radiographic identifier has a shape of a reflection-asymmetric character.

6. The method of claim **2**, wherein the radiographic identifier comprises a material having a first radiopacity that is different from a second radiopacity of the plurality of commissural posts, which material is coupled to each of the plurality of commissural posts.

7. The method of claim **2**, wherein the native commissures of the native heart valve include a first native commissure between a left coronary sinus and a right coronary sinus of the native heart valve and wherein rotationally aligning comprises rotationally aligning one of the plurality of commissural posts with the first native commissure.

8. The method of claim **2**, wherein at least one of the plurality of commissure posts includes an opening that serves as the at least one radiographic identifier.

9. The method of claim **2**, wherein the at least one radiographic identifier is positioned on at least one of the plurality of commissure posts.

10. The method of claim **9**, wherein at least one of the plurality of commissure posts includes an opening and the radiographic identifier is positioned adjacent the opening.

11. The method of claim **10**, wherein the opening is a reflection-symmetric shape.

12. The method of claim **2**, wherein at least one of the plurality of commissural posts is shaped so as to define both reflection asymmetrical radiographic identifier and a reflection-symmetric shape.

13. The method of claim **1**, wherein the radiographic identifier is shaped like a letter of the alphabet.

14. The method of claim **1**, wherein the radiographic identifier is shaped like a number.

15. The method of claim **1**, wherein the radiographic identifier is a slit.

16. The method of claim **1**, wherein the radiographic identifier is shaped to be reflection-asymmetric about a longitudinal axis which is generally parallel with a central longitudinal axis of the valve prosthesis when the valve prosthesis assumes the collapsed configuration.

17. The method of claim **1**, wherein the radiographic identifier has a shape of a reflection-asymmetric character.

18. The method of claim **1**, wherein the valve prosthesis includes a frame, wherein the radiographic identifier comprises a material having a first radiopacity that is different from a second radiopacity of the frame, which material is coupled to the frame.

19. The method of claim **1**, wherein the valve prosthesis includes a frame, wherein at least a portion of the frame is shaped so as to define both reflection asymmetrical radiographic identifier and a reflection-symmetric shape.

20. The method of claim **1**, wherein the valve prosthesis includes a frame, wherein at least a portion of the frame includes an opening that serves as the at least one radiographic identifier.

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